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# History Sheet

| Rev | Date | Reason for revision | Revised by |
|---|---|---|---|
| A | 11 Jul 2001 | This manual number and referenced ABCN number were changed to reflect the new project numbering scheme. As a result, the revision numbers reflect Revision 0 for the ABCN and Revision A for this Quality Assurance Manual. These numbering changes have no effect on document content, and are purely administrative.<br>Incorporate DOE Comments<br>Ref: 24590-WTP-ABCN-ESH-01-010<br>24590-WTP-QAM-QA-01-001, Rev. A, when approved, supercedes QAM-24590-01-00001, Rev. B | G. Grant |
| 0 | 31 Aug 2001 | Document approved for issuance per DOE Letter 01-OSR-0285 | G. Grant |
| 0a | 2 Jan 2002 | Incorporates 24590-WTP-ABCN-ESH-01-023 Rev 0 changes (contractor-approved ABCN). | G Grant |
| 1 | 12 July 2002 | This revision is submitted as the annual Contract Deliverable and incorporates changes resulting from project organizational and responsibility changes, clarifications, and general enhancements of implementation strategy and policy based on project operating experience. | D. Canazaro |
| 2 | 11/04/2002 | This revision incorporates the roles and responsibilities established under the WTP organization transition, as well as resolution of comments received from DOE OSR from issuance of revision 1. This revision includes incorporation of QARD specific requirements for document change reviews to be now applicable to the entire program. | D. Canazaro |
| 3 | 01/06/2003 | This revision incorporates the roles and responsibilities established under the WTP re-organization and editorial changes, as well as, incorporation of QARD revision 11 (Model Development and Use). | D. Canazaro |
| 3a | 05/14/2003 | Revision 3a incorporates the roles and responsibilities established under the recent WTP re-organization. This revision also includes minor editorial corrections to Policies Q-02.4, Q-06.1 and Q-08.1. | D. Canazaro |
| 4 | 07/10/2003 | This revision is submitted as the annual Contract Deliverable and clarifies requirements and qualifications for NDE and for testing. | J. Smith |
| 4a | 08/21/2003 | This revision incorporates revision 13 of DOE/RW-0333P, Quality Assurance Program Description (QARD). This revision also revises reference to SNT-TC-1A to read: "SNT-TC-1A June 1980 through 2001 edition, all inclusive. | M. Cochrane |
| 4b | 10/17/2003 | This revision incorporates changes to support the commissioning phase of the project, changes related to responsibilities for the WTP ISMS program, and clarification of verbiage in the QARD specific sections. These changes are marked with revision bars. This revision also includes minor editorial corrections to Policies (these changes are not marked with revision bars). Content of this revision continues to satisfy Section (b) (3) of 10 CFR 830, Subpart A, *Quality Assurance Requirements*. | M. Cochrane |

# History Sheet

| Rev | Date | Reason for revision | Revised by |
|---|---|---|---|
| 5 | 07/15/2004 | This revision updates the "Project Management" organization chart, responsibilities, and clarifies a reference to 10 CFR Part 830, Subpart A, Section 830.121(b)(3). Changes were made to clarify and better align with the intent of language in Policy Q-04.1, paragraph 3.1.3. These changes are marked with revision bars. This revision also includes minor editorial corrections to Policies (these changes are not marked with revision bars).<br>These changes continue to satisfy the WTP contract quality assurance requirements and do not adversely affect safety or represent a reduction from current regulatory commitments. | M. Cochrane |
| 5a | 11/8/2004 | This revision revised and reorganized Policy Q-01.1 to reflect revised "Project Management" organization chart. This revision also revises:<br>Policy Q-03.2 to clarify compliance of the policy to Subpart 2.7 of NQA-2<br>Policy Q-07.1 to provide an alternative approach for the dedication of commercial grade items.<br>Policy Q-09.1, to clarify independence of individuals performing acceptance of special processes.<br>Policy Q-16.1, to add the requirements for processing Industrial Safety and Health CARs.<br>Additional minor changes were made to detail and clarify requirements or responsibilities in Policies Q-15.1, Q-16.2.<br>Policies that include changes that are technical or non-editorial in nature will be marked with revision bars. Minor editorial corrections will be shown as revision 5a, however, changes are not marked with revision bars.<br>These changes continue to satisfy the WTP contract quality assurance requirements and do not adversely affect safety or represent a reduction from current regulatory commitments. | M. Cochrane |
| 6 | 08/01/2005 | This revision incorporates US Department of Energy (DOE) Order 414.1B, *Quality Assurance*. The updated DOE Order (DOE O 414.1B) resulted in the addition of new Policy Q-15.2, "Control of Suspect/Counterfeit Items." (CCN 100973).<br>Policy Q-01.1 and Supplements I and III were revised to reflect organizational changes and responsibilities.<br>Policy Q-02.1: Para. 1.6.1 was revised to remove Project Safety Committee concurrence with QAM revisions and para 1.1.5 and Figure 2 were revised from "DOE O 414.1A" to "DOE O 414.1B." Paragraphs 1.2.1, 1.3.1, 1.4.1, and 1.10.1 were revised to provide consistency in identifying quality-affecting items and activities. Created new paragraphs 1.1.6 and 1.1.7 to facilitate the application of consensus standards.<br>Policy Q-02.2 was revised to reflect organizational changes and responsibilities. Paragraph 3.3.3.A was revised for clarity.<br>Policy Q-03.1 was revised to reflect organizational changes and responsibilities.<br>Policy Q-4.1: Paragraphs 6.1.1.A, 6.2.1, and 6.5.1.D were revised to provide consistency in identifying quality-affecting items and activities.<br>Policy Q-06.1 was revised to reflect organizational changes and | M. Cochrane |

# History Sheet

| Rev | Date | Reason for revision | Revised by |
|---|---|---|---|
| | | responsibilities (Section 6).<br>Policy Q-07.1 was revised to renumber Section 4 and to update the "Manager of Construction" title. Paragraph 1.2 was revised to provide consistency in identifying quality-affecting items and activities. The policy was also revised to reflect organizational changes and responsibilities.<br>Policy Q-15.1: Paragraphs 1.2 and 3.2.4 were revised to provide consistency in identifying quality-affecting items and activities.<br>Policy Q-17.1 was revised to remove the word "radiographs" from paragraph 3.6. (CCN 082747)<br>Appendix A was renamed and revised to remove "QL."<br>Supplement I: Section 5 was revised to reflect organizational changes and update responsibilities.<br>Supplement III: Section 5 was revised to reflect organizational changes and update responsibilities.<br>Policies that include changes that are technical or non-editorial in nature will be marked with revision bars. Minor editorial corrections are not marked with revision bars.<br>These changes continue to satisfy the WTP contract quality assurance requirements and do not adversely affect safety or represent a reduction from current regulatory commitments. | |

# Revision Status Sheet

| Document Part | Title | Revision | Pages w/Tracked Revisions |
|---|---|---|---|
| Front Matter | N/A | 6 | iii, iv, v, vi, vii, viii |
| Policy Q-01.1 | Project Organization | 6 | Q-01.1-2 through 14 |
| Policy Q-02.1 | Quality Assurance Program | 6 | Q-02.1-1, -2, -3, -5, -6, -7, -9 |
| Policy Q-02.2 | Personnel Training and Qualification | 6 | Q-02.2-3, -5 |
| Policy Q-02.3 | Auditor/Lead Auditor Qualification and Certification | 6 | |
| Policy Q-02.4 | Special Reviews | 6 | |
| Policy Q-03.1 | Design Control | 6 | Q-03.1-10 |
| Policy Q-03.2 | Software Quality | 6 | |
| Policy Q-04.1 | Procurement Document Control | 6 | Q-04.1-4, -5 |
| Policy Q-05.1 | Instructions, Procedures, and Drawings | 6 | |
| Policy Q-06.1 | Document Control | 6 | Q-06.1-5 |
| Policy Q-07.1 | Control of Purchased Items and Services | 6 | Q-07.1-1, -10, -11 |
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| Policy Q-09.1 | Control of Special Processes | 6 | |
| Policy Q-10.1 | Inspection | 6 | |
| Policy Q-11.1 | Test Control | 6 | |
| Policy Q-12.1 | Control of Measuring and Test Equipment | 6 | |
| Policy Q-12.2 | Installed Process Instrumentation | 6 | |
| Policy Q-13.1 | Handling, Storage, and Shipping | 6 | |
| Policy Q-14.1 | Inspection, Test and Operating Status | 6 | |
| Policy Q-15.1 | Control of Nonconforming Items | 6 | Q-15.1-1, -2 |
| Policy Q-15.2 | Control of Suspect/Counterfeit Items | 6 | New Policy |
| Policy Q-16.1 | Corrective Action | 6 | |
| Policy Q-16.2 | Stop Work | 6 | |
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# Foreword

The Quality Assurance (QA) Policies in this manual establish the quality assurance requirements for Bechtel National, Inc. (BNI) at the Waste Treatment Plant (WTP) Project. They meet the requirements specified in the following sources:

1 US Code of Federal Regulations (CFR) 10 CFR 830, Subpart A, Quality Assurance Requirements.

2 US Department of Energy (DOE) Order 414.1B, Quality Assurance.

3 American National Standard, ASME NQA-1-1989 (NQA-1), Quality Assurance Program Requirements for Nuclear Facilities.

4 Office of Civilian Radioactive Waste Management, DOE/RW-0333P (Rev. 13), Quality Assurance Requirements and Description (QARD).

5 ASME NQA-2a-1990, *Quality Assurance Requirements for Nuclear Facility Applications*, Subpart 2.7, *Quality Assurance Requirements of Computer Software for Nuclear Facility Applications*

This manual contains policies that are applicable to the facilities and services being designed, constructed, commissioned, operated, managed, or provided under BNI's contract with the US Department of Energy, Office of River Protection (DOE-ORP). It applies to work that takes place at or for the WTP Project (project) and to suppliers and subcontractors, as specified by procurement documents, such as design, manufacturing, or analytical laboratory services. In addition, these policies apply to spare/replacement part procurement; repair; modifications; maintenance; in-service and/or non-destructive examinations, inspections, or testing; technical analysis and support; and other quality-affecting activities.

The requirements found in each policy reflect the integration of applicable requirements from the above referenced sources. The requirements are either consensus requirements, specific requirements, or project-imposed requirements. A consensus requirement is a requirement that serves as a baseline requirement for the project. A baseline requirement represents a single requirement that meets the intent of the individual requirements identified from each source. Specific requirements have only narrow scope application and are not applied across the project. Project-imposed requirements are those that reflect good management practice.

This integration of requirements allows the development of one project quality assurance program composed of the quality assurance manual policies and the necessary implementing documents (i.e., procedures) for the project. This concept of developing a single-project quality assurance program simplifies compliance by simultaneously satisfying requirements from multiple requirements sources. This concept also allows implementing documents to be developed from the quality assurance policies rather than referring to the individual source requirements.

**Overview**

The project QA program (defined by the QA manual and associated implementing documents) directs the achievement and verification of quality. The project quality assurance manager is responsible for the overall QA program-its development, maintenance, verification, and continuing improvement-and is the approval authority for matters pertaining to its interpretation and implementation. Line organizations are responsible for implementing and meeting the requirements of the QA program. Each individual is

responsible for the quality of his or her work. Line management is ultimately responsible to see that quality is achieved.

The project QA program provides an important function in implementing the Integrated Safety Management System (ISMS). The QA program is an integral part of all the processes by which (a) work is prioritized, (b) clear roles and responsibilities are established, (c) individuals performing work have competence commensurate with their responsibilities, (d) hazards are analyzed, (e) standards and controls are identified and applied, (f) work is performed, and (g) performance is evaluated and improved.

The project QA program establishes controls within its implementing documents that are consistent with the risks associated with the activity, and that take into account the work to be performed and the associated hazards. Effective implementation of the quality assurance program will also provide processes and tools to support principles and functions of the Safety Management System Policy (DOE P 450.4) and related portions of the DOE Acquisition Regulation (DEAR, 48 CFR 970.5204-2).

# Policy Statement

One of the fundamental aspects of any quality assurance (QA) program is that the individuals performing the work determine the quality that is to be achieved. Though plans, procedures, and instructions are a basic part of any quality program, it should be recognized that people make quality happen. Each individual, when properly trained and motivated, must achieve the highest quality of performance of which he or she is capable.

It is the policy of Bechtel National, Inc. (BNI) to design, construct, and commission the Waste Treatment and Immobilization Plant (WTP) so that it can be maintained and operated in such a manner as to ensure the health and safety of the public, the personnel onsite, and protect the environment. One way to accomplish this critical objective is to have an aggressive and comprehensive quality assurance program in place for those activities which can impact safety and quality.

The Project Director has directed the establishment of a formal and comprehensive QA program for the project. This program places accountability for quality on each person working on the project. In addition, it emphasizes the creation of an atmosphere in the workplace where the reporting and the resolution of conditions adverse to quality are encouraged and expected at all levels.

The QA program identifies those requirements that shall be implemented to satisfy the contractual requirements. The QA program includes the associated procedures and instructions which implement the program requirements.

Quality assurance objectives shall not be subordinate to cost or schedule objectives. To ensure compliance with the QA program requirements, independent verifications and assessments shall be conducted to provide management a measure of the program's effectiveness and adequacy in meeting the requirements of the QA program and its implementing procedures and instructions.

Conflicts involving implementation of the requirements of the QA program shall be resolved by the QA Manager or, if deemed necessary, the BNI Corporate QA Manager. In those instances when BNI has imposed implementation of parts of the QA program to suppliers and/or subcontractors, BNI retains responsibility to ensure the adequacy of their respective program.

J. P. Henschel
Project Director

# Policy Q-01.1 Project Organization

## 1 Purpose

1.1 This policy identifies requirements and responsibilities for organizations that provide for the achievement of safety and quality in items produced and activities performed.

## 2 Applicability

2.1 This policy applies to the organizations that prescribe, perform, or verify activities affecting safety and quality, including those having responsibility for planning and scheduling. An organizational chart included in Figure 1 displays the relationship of organizations having principal roles in the Quality Assurance (QA) Program.

## 3 Responsibilities

### 3.1 All Managers

3.1.1 All managers are responsible for:

3.1.1.A Incorporating the Integrated Safety Management System (ISMS) provisions into work processes.

3.1.1.B Complying with regulatory and contractual requirements.

3.1.1.C Developing and maintaining a comprehensive set of management controls.

3.1.1.D Interfacing and communicating with other managers in accomplishing facility design, construction, and commissioning activities.

3.1.1.E Promoting the management concept of Six Sigma among all members of their organizations.

3.1.1.F Creating an atmosphere in the workplace where reporting and resolving conditions adverse to quality are encouraged at all levels.

3.1.1.G Stopping activities within their areas of responsibility that do not comply with the Authorization Basis (AB) and/or regulatory requirements.

3.1.1.H Fully supporting the Safety, QA, and Employee Concerns Programs, thereby assuring that all work performed under their cognizance will conform to and support the requirements of this manual.

## 3.2 Project Director

3.2.1 The Project Director has the overall responsibility for the development, design, procurement, modification, maintenance, construction, commissioning, and operations of the project, including the authority to stop unsafe or unsatisfactory work and control further processing, delivery, or installation of nonconforming material. The Project Director reviews the status and adequacy of the Health and Safety and QA Programs by reviewing reports prepared by the Safety Assurance and QA Managers at least annually. The Project Director has delegated responsibility for engineering, procurement, and construction (EPC), modifications, records management, commissioning and operations, and proper implementation of the QA Program for these activities to the Project Manager. The Project Director has delegated responsibility to establish, maintain, and verify proper implementation of the Industrial Health and Safety and site environmental compliance program to the Safety Assurance Manager and the QA Program to the QA Manager. The Project Director shall retain the responsibility for assuring that the authority and independence of the Safety Assurance and QA Managers are such that they can effectively assure the conformance to safety and quality requirements. The Project Director ensures that the Employee Concerns Program is independent and that employees are provided with an avenue to raise issues or concerns to the attention of management without fear of harassment, intimidation, retaliation, or discrimination.

3.2.2 The Project Director is responsible for the following major functions:

3.2.2.A Establishing the overall vision for the project and instilling a culture of excellence for safety and quality, including performance expectations.

3.2.2.B Establishing and implementing the organizational structure of the project.

3.2.2.C Providing a single point of accountability with the U.S. Department of Energy (DOE), Office of River Protection (ORP).

3.2.2.D Integrating the activities of the Project Manager and Business Services.

3.2.2.E Integrating nuclear and industrial safety, quality, and environmental protection into work activities.

3.2.2.F Developing management assessment policies.

3.2.2.G Acting on recommendations from corporate quality and safety oversight.

3.2.3 The Project Director has the responsibility to stop project activities that do not comply with the AB and/or regulatory requirements.

## 3.3 Deputy Project Director

3.3.1 The Deputy Project Director reports directly to the Project Director and performs duties as directed.

## 3.4 Employee Concerns Manager

3.4.1 The Employee Concerns Manager reports to the Project Director and is responsible for creating a framework for the identifying, reporting, and resolving employee concerns.

3.4.2 The Employee Concerns Manager is responsible for the following major functions:

3.4.2.A Developing, maintaining, and implementing the project Employee Concerns Program.

3.4.2.B Informing employees of the availability of the Employee Concerns Program and their rights to raise concerns related to the environment, safety, health, or management of DOE-related activities without any fear of harassment, intimidation, retaliation, or discrimination.

3.4.2.C Evaluating and attempting to resolve employee concerns in a manner that protects the health and safety of employees and the public, ensures effective and efficient operation of programs, and uses alternative dispute resolution techniques whenever appropriate.

3.4.2.D Providing timely notification to the DOE of any significant concerns or allegations of retaliation.

3.4.2.E Conducting self-assessments to measure effectiveness of the Employee Concerns Program.

3.4.2.F Performing oversight of subcontractors' employee concerns programs.

## 3.5 Quality Assurance Manager

3.5.1 The QA Manager has the functional authority, independence, and responsibility to assure the effective implementation of and compliance to the QA Program. Consistent with this authority is the responsibility to document interpretations of those activities to which the QA Manual (QAM) applies and the extent to which the QAM applies to those activities. The QA Manager has no unrelated duties that would preclude full attention to assigned responsibilities.

3.5.2 The QA Manager reports directly to Bechtel National, Inc. (BNI) QA for program definition and functionally to the Project Director for QA matters. The QA Manager is responsible to ensure that an appropriate QA Program, the scope of which includes all the systems and activities that affect safety and quality, is established and implemented in accordance with the requirements of the QAM. The QA Manager reviews project activities with the goal of identifying areas where changes could lead to improvements in safety and/or quality. The QA Manager has the authority to cross organizational lines to identify quality problems, to initiate, recommend, or provide solutions, and to verify implementation.

**Policy Q-01.1 Project Organization**

3.5.3 The QA Manager is responsible for the following major functions:

3.5.3.A Providing guidance and oversight for the project based on applicable requirements of 10 CFR 830, Subpart A, DOE Order 414.1B, DOE/RW-0333P, Revision 13, NQA-1 (1989), and NQA-2a-1990.

3.5.3.B Conducting independent assessments (audits and surveillances).

3.5.3.C Providing guidance on quality and safety to the project organizations.

3.5.3.D Performing evaluations and self-assessments on a planned and periodic basis to verify the QA Program is being effectively implemented.

3.5.3.E Directing that work will be stopped on nonconforming materials or activities if:

3.5.3.E.1. Other corrective action processes are ineffective in protecting the health and safety of the public and/or plant personnel.

3.5.3.E.2. Continued work will require significant rework or repair to back fit corrective action.

3.5.3.E.3. An organization, department, group, section, or individual, by a repetitive failure to comply with technical or administrative controls, contributes to a condition that is a significant QA Program deficiency.

3.5.3.F Determining when appropriate actions have been taken to lift a stop work order to allow work to proceed.

3.5.3.G Providing for the review and acceptance of contractor and vendor QA programs.

3.5.3.H Providing for the review of procedures and other quality-related documents.

3.5.3.I Providing a working interface and line of communication with other departments, appropriate industry representatives, and regulatory groups for QA matters.

3.5.3.J Interfacing with the ORP regulators for onsite inspections.

3.5.3.K Establishing indoctrination and training programs for QA and Quality Control (QC) personnel.

3.5.3.L Providing input for QA indoctrination of personnel outside of the QA organization.

3.5.3.M Issuing periodic reports to the Project Director and appropriate management on the status of quality activities.

3.5.3.N Notifying the Project Director, or appropriate management, of any significant conditions adverse to quality.

3.5.3.O Trending conditions adverse to quality.

3.5.3.P Providing Price-Anderson Amendments Act (PAAA) Program identification, documentation, and supporting function for the Project.

3.5.3.Q Developing and maintaining the QAM.

3.5.3.R Developing and maintaining the QA Provisions Document (QAPD).

3.5.3.S Developing and maintaining the Suspect/Counterfeit Items Program.

3.5.3.T Providing necessary resources to the project organizations.

3.5.4 The QA Manager may delegate activities to other organizational elements; however, the QA Manager retains full responsibility for the QA Program.

## 3.6 Safety Assurance Manager

3.6.1 The Safety Assurance Manager reports directly to BNI Environmental, Safety, and Health for program definition and functionally to the Project Director for industrial safety, health, and environmental compliance matters. The Safety Assurance Manager is responsible for ensuring that an appropriate industrial safety program, the scope of which includes all activities that affect industrial safety, is established and implemented. The Safety Assurance Manager is responsible to provide services to assure that uniform industrial safety, regulatory adequacy, and environmental compliance is achieved.

3.6.2 The Safety Assurance Manager is responsible for providing the following major functions in a safe, reliable, and efficient manner in accordance with policies and applicable laws, regulations, and licenses:

3.6.2.A Implementing, evaluating, and continuously improving the industrial safety program.

3.6.2.B Identifying industrial safety regulatory requirements.

3.6.2.C Supporting the project in industrial hygiene and safety.

3.6.2.D Providing positions and interpretations on industrial health and safety regulatory requirements.

3.6.2.E Ensuring environmental compliance at the jobsite.

3.6.2.F Providing the Occurrence Reporting Program identification, documentation, and supporting function for the project.

3.6.2.G Providing necessary resources to the project organizations.

3.6.2.H Maintaining and improving the project ISMS program.

## 3.7 Project Manager

3.7.1 The Project Manager reports directly to the Project Director and is responsible for the design, procurement, construction, modification, maintenance, commissioning, and operations of the project, ensuring that appropriate policies are provided for these activities. The Project Manager has the authority to stop unsafe or unsatisfactory work and control further processing, delivery, or installation of nonconforming material. Responsibility for the engineering, construction, modifications, records management, commissioning, operations during the operations phase, and proper implementation of the QA Program for these activities is delegated to the direct reports of the Project Manager.

3.7.2 The Project Manager is responsible for the following major functions:

3.7.2.A Integrating nuclear and industrial safety, quality, and environmental protection into work activities.

3.7.2.B Promoting a culture of excellence for safety and quality.

3.7.2.C Managing the project organizations and the execution of work.

3.7.2.D Managing the facility and process design, construction, and procurement.

3.7.2.E Assuring implementation of management assessment policies.

3.7.2.F Ensuring all required items and services are procured and the necessary funds are committed.

3.7.2.G Verifying that consistent procedures and approaches are employed to design, procure, and construct the project facilities in a safe and efficient manner.

3.7.2.H Integrating the activities of the Manager of Engineering, Manager of Construction, Acquisition Services Manager, Operations Manager, and Manager of Project Controls.

3.7.2.I Integrating and managing acceptance testing, commissioning, and operations into the overall completion of the project.

3.7.2.J Initiating action to resolve problems to assure program/project objectives and schedules are met and work is performed within budget and according to specifications.

3.7.2.K Overseeing management assessments of the project organizations to ensure that the project is delivered to the standards of quality and safety and to the customer and Bechtel expectations.

3.7.2.L Assuring the project organizations are monitoring and assessing their compliance with all the processes, procedures, and regulatory requirements.

3.7.2.M Providing primary interface for and management of the coordination of the Washington Group International (WGI) contract scope of work.

3.7.2.N Overseeing and helping maintain the relationship with stakeholders such as the Defense Nuclear Facilities Safety Board, the Washington State Department of Ecology, and the Hanford Advisory Board.

3.7.2.O Overseeing the management and implementation of the Root Cause Analysis (RCA) process and developing and implementing a lessons learned program.

3.7.2.P Ensuring that RCAs on significant quality issues are completed and implemented effectively in a timely fashion and communicated with the customer.

3.7.2.Q Ensuring that best practices/lessons learned are captured and disseminated.

3.7.2.R Ensuring Six Sigma processes are used to support continuous improvement.

3.7.2.S Monitoring progress to ensure work is performed as defined and initiating action to ensure commitments are met.

3.7.2.T Providing direction and necessary resources to the Assistant Project Managers.

## 3.8 Deputy Project Manager

3.8.1 The Deputy Project Manager reports directly to the Project Manager and performs duties as directed.

## 3.9 Assistant Project Managers

3.9.1 The Assistant Project Managers report directly to the Project Manager and perform duties as directed.

## 3.10 Manager of Project Controls

3.10.1 The Manager of Project Controls reports directly to the Project Manager and is responsible to provide efficient project controls services in accordance with policies and all applicable laws, regulations, and licenses.

3.10.2 The Manager of Project Controls is responsible for the following major functions:

3.10.2.A Effectively executing the Project Controls Programs.

3.10.2.B Developing, interpreting, and executing policy, objectives, and standards applicable to cost and schedule control and analysis activities.

3.10.2.C Developing and maintaining integrated technical, schedule, and cost baselines.

3.10.2.D Evaluating performance data and developing forecasts and identifying problems.

3.10.2.E Providing necessary resources to the project organizations.

## 3.11 Manager of Engineering

3.11.1 The Manager of Engineering reports to the Project Manager and is the Design Authority. The Manager of Engineering is responsible for ensuring that the project facilities are designed, procured, and constructed in a safe, reliable, and efficient manner in accordance with policies and all applicable laws, regulations, the AB, and technical requirements.

3.11.2 The Manager of Engineering is responsible for the following major functions:

3.11.2.A Integrating nuclear and industrial safety, quality, and environmental protection into design activities.

3.11.2.B Managing facility and process design, environmental, radiological and nuclear safety, and document control.

3.11.2.C Providing technical expertise to the engineering organization.

3.11.2.D Assuring uniform technical and regulatory adequacy of engineering activities.

3.11.2.E Ensuring technical accuracy of requirements specified in procurement documents.

3.11.2.F Providing functional direction to project engineering for implementation of engineering activities as the project design agency.

3.11.2.G Ensuring environmental and nuclear safety requirements are implemented in procurement and design documents.

3.11.2.H Establishing and maintaining facility design requirements, system descriptions, basis of design, and other design criteria.

3.11.2.I Designing features to implement the design requirements for occupational radiation protection including features for ensuring exposure of personnel during operation is As Low As Reasonably Achievable (ALARA).

3.11.2.J Designing fire prevention, detection, and suppression features in compliance with state and federal requirements.

3.11.2.K Preparing specifications for procurement of structures, systems, components, and services.

3.11.2.L Determining the applicability of the grading process.

3.11.2.M Overseeing design, including periodic reviews involving the DOE.

3.11.2.N Interfacing with regulators, stakeholders, and the DOE on project design issues.

3.11.2.O Developing and implementing the configuration management program to control the safety and design bases.

3.11.2.P Managing research and technology activities, including development and execution of the Research and Technology Plan, as well as completion of WTP contract deliverables and scheduled Research and Technology activities conducted by subcontractors.

3.11.2.Q Incorporating deactivation and decommissioning features into facility design.

3.11.2.R Providing necessary resources to the project organizations.

## 3.12 Deputy Manager of Engineering

3.12.1 The Deputy Manager of Engineering reports directly to the Manager of Engineering and performs duties as directed.

## 3.13 Environmental and Nuclear Safety Manager

3.13.1 The Environmental and Nuclear Safety (E&NS) Manager reports directly to the Manager of Engineering and is responsible to provide services to assure that uniform technical and regulatory adequacy is achieved.

3.13.2 The E&NS Manager is responsible for providing the following major functions in a safe, reliable, and efficient manner in accordance with policies and applicable laws, regulations, and licenses:

3.13.2.A Implementing, evaluating, and continuously improving a rigorous standards-based E&NS program.

3.13.2.B Identifying E&NS regulatory requirements.

3.13.2.C Maintaining facilities' AB documentation other than the QAM.

3.13.2.D Developing and providing oversight for safety programs in AB compliance, nuclear safety, criticality safety, fire protection, and radiation protection.

3.13.2.E Developing safety basis and safety-related performance measures for nuclear safety.

3.13.2.F Interfacing with regulators, stakeholders, and Hanford site contractors on nuclear safety and regulatory compliance matters.

3.13.2.G Assisting the DOE in obtaining all required project permits.

3.13.2.H Providing positions and interpretations on the regulatory documents to which the project is committed.

3.13.2.I Reviewing the technical accuracy of environmental and nuclear safety requirements specified in procurement and design documents.

3.13.2.J Providing necessary resources to the project organizations.

## 3.14 Project Administrative Services Manager

3.14.1 The Project Administrative Services Manager reports to the Manager of Engineering and is responsible for execution and completion of activities associated with the document control functions, in a safe, reliable, and efficient manner in accordance with project standards, schedules, and policies and applicable laws, regulations, permits, and licenses.

3.14.2 The Project Administrative Services Manager is responsible for the following major functions:

3.14.2.A Providing the processes, tools (including development and maintenance of a records management system), and procedures for managing all project document control and records management activities.

3.14.2.B Implementing and maintaining the management of QA records.

3.14.2.C Providing necessary administrative resources to the project organizations.

## 3.15 Manager of Construction

3.15.1 The Manager of Construction reports to the Project Manager and is responsible to provide construction services to assure uniform technical and regulatory adequacy of construction activities.

3.15.2 The Manager of Construction is responsible for providing the following major functions in a safe, reliable, and efficient manner in accordance with policies and applicable laws, regulations, permits, and licenses:

3.15.2.A Providing the Construction, Procurement, and Acceptance Testing Plan.

3.15.2.B Providing constructability reviews.

3.15.2.C Implementing appropriate construction methods and scheduling and delivering labor, construction equipment, and materials.

3.15.2.D Ensuring industrial safety, environmental protection, quality, and security, and managing construction, properties, and facilities, including warehouses and laydowns.

3.15.2.E Managing subcontractors, supervising direct hires and force account personnel, and fostering positive labor relations.

3.15.2.F Providing construction testing and inspection services.

3.15.2.G Implementing procedures and training to enhance construction safety.

3.15.2.H Supporting the incident reporting system for construction-related incidents.

3.15.2.I Providing necessary resources to the project organizations.

### 3.16 Acquisitions Services Manager

3.16.1 The Acquisition Services Manager reports to the Project Manager and is responsible for providing the processes and procedures for procuring items and services, including the formulating and administering of subcontracts.

3.16.2 The Acquisition Services Manager is responsible for the following major functions:

3.16.2.A Providing the processes and procedures for procuring items and services, including the formulation and administration of purchase orders and subcontracts that assure the flowdown of quality and safety requirements to suppliers and subcontractors.

3.16.2.B Soliciting and receiving proposals and ensuring that requirements specified in the procurement documents, including quality requirements, are accurately transcribed into the final purchase documents.

3.16.2.C Formulating and administering subcontracts, ensuring that requirements specified in the subcontract documents, including quality requirements, are accurately transcribed into the subcontract documents.

3.16.2.D Implementing a source verification program to assure suppliers', and subtier suppliers', as applicable, compliance with procurement document requirements.

3.16.2.E Providing necessary resources to the project organizations.

### 3.17 Operations Manager

3.17.1 The Operations Manager reports to the Project Manager and is responsible to ensure that the project facilities are tested, commissioned, operated, and maintained in a safe, reliable, and efficient manner in accordance with policies and all applicable laws, regulations, the AB, and technical requirements.

3.17.2 The Operations Manager is responsible for the following major functions:

3.17.2.A Managing and integrating the Start-up and Commissioning Programs.

3.17.2.B Defining operations requirements that affect the project design features or concepts, establishing system reliability, availability, maintainability, and inspectability criteria, and establishing the process control strategy.

3.17.2.C Developing plans and preparing reports for all process verification and product qualification testing.

3.17.2.D Developing and maintaining operating procedures.

3.17.2.E Developing and maintaining the readiness review program to support commissioning.

3.17.2.F Managing Training department activities and implementation, control, and maintenance of the training matrix for tracking training of personnel and for determining the status of the training program.

3.17.2.G Providing necessary resources to the project organizations.

3.17.2.H Ensuring that, after acceptance of a system by Commissioning, processing plant modifications and temporary plant changes are accomplished in accordance with the requirements for design change control.

## 3.18 Start-up Manager

3.18.1 The Start-up Manager reports to the Operations Manager and is responsible for acceptance and start-up testing in a safe, reliable, and efficient manner in accordance with policies, applicable laws, regulations, the AB, and technical requirements.

3.18.2 The Start-up Manager is responsible for the following major functions:

3.18.2.A Developing the objectives and scope for the start-up program.

3.18.2.B Verifying and validating operations procedures and maintenance procedures during performance of testing.

3.18.2.C Managing acceptance and start-up testing.

3.18.2.D Managing and integrating commissioning support subcontractor(s) if utilized.

3.18.2.E Providing information from the start-up program to the operations, training, procedures, and maintenance groups for verification and validation of operating administrative controls.

## 3.19 Commissioning/Training Manager

3.19.1 The Commissioning/Training Manager reports to the Operations Manager and is responsible for project facilities commissioning, operation, and maintenance in a safe, reliable, and efficient manner in accordance with policies and all applicable laws, regulations, the AB, and technical requirements.

3.19.2 The Commissioning/Training Manager is responsible for the following major functions:

3.19.2.A Developing and evaluating proposed changes to the commissioning program.

3.19.2.B Verifying and validating operations and maintenance procedures during the performance of testing.

3.19.2.C Managing hot commissioning and facility turnover.

3.19.2.D Managing and integrating commissioning support subcontractor(s) if utilized.

3.19.2.E Ensuring that operators become and remain familiar with the features and limitations of equipment including the design of the facility.

3.19.2.F Providing information from the start-up program to the operations, training, procedures, and maintenance groups for verification and validation of operating administrative controls.

3.19.2.G Providing relevant input, coordination, and necessary resources to the project organizations.

## 3.20 Business Services Manager

3.20.1 The Business Services Manager reports directly to the Project Director and is responsible to provide business services to assure regulatory adequacy of business activities.

3.20.2 The Business Services Manager is responsible for providing the following major functions in an efficient manner in accordance with policies and all applicable laws, regulations, and licenses:

3.20.2.A Managing all business and administrative functions, including Contracts, Human Resources, Information Technology, Controller, WGI Business Services, and Support Services.

3.20.2.B Implementing and maintaining the Information Management System.

3.20.2.C Implementing and maintaining the Project Risk Management Program.

3.20.2.D Providing necessary resources to the project organizations.

## 3.21 All Personnel

3.21.1 All project employees are responsible for:

3.21.1.A Achieving acceptable quality during the performance of work activities.

3.21.1.B Safely accomplishing work activities in accordance with instructions, procedures, and drawings.

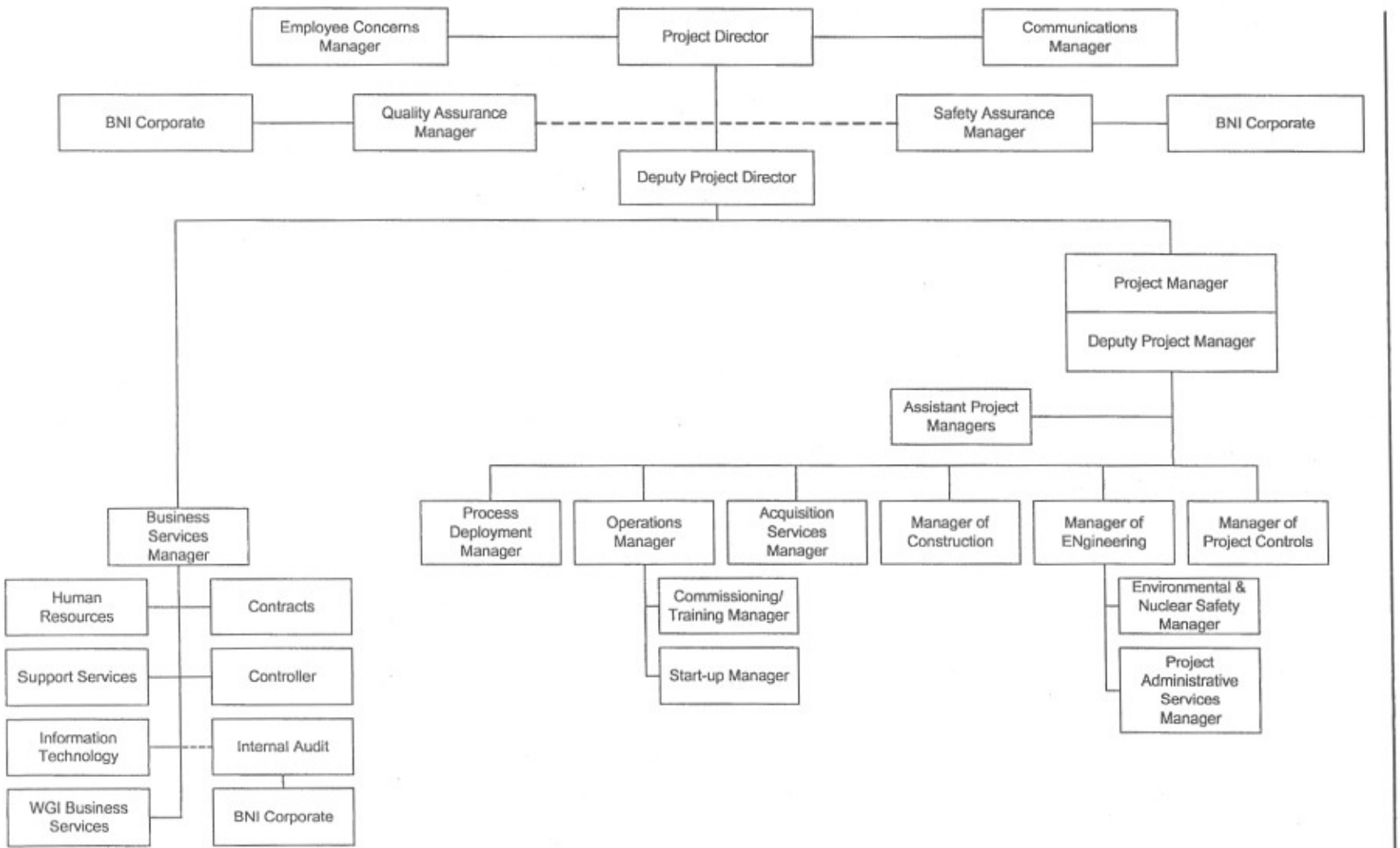
3.21.1.C Stopping work activities and informing their supervisors when it appears that adherence to a procedure is not possible or may result in an unsafe condition.

3.21.1.D Promptly identifying and reporting safety and quality deficiencies to their supervisors.

3.21.1.E Ensuring that the WTP is designed, constructed, tested, and commissioned in a safe, reliable, and efficient manner in accordance with policies and procedures and all applicable laws, regulations, the AB, and technical requirements.

**Policy Q-01.1 Project Organization**

# Figure 1: Project Management



# Policy Q-02.1 Quality Assurance Program

## 1 Quality Assurance Program

### 1.1 General

1.1.1 The Bechtel National, Inc. (BNI) Quality Assurance (QA) program has been established to control the activities performed within the scope of designing, constructing, and commissioning the Waste Treatment Plant (hereafter referred to as the project). The key elements of the QA program include a defined work scope, a planned methodology of quality management, clear work control elements, a process for documenting nonconformances and corrective actions, an indoctrination and training program, and provisions for independent and management assessments.

1.1.2 The QA program is a management system designed to promote the effective and efficient achievement of performance objectives through:

1.1.2.A Planning and documenting requirements for items, processes, and services.

1.1.2.B Controlling activities affecting the quality of those items, processes, and services.

1.1.2.C Demonstrating adequacy of work and verifying the achievement of required quality.

1.1.2.D Analyzing and correcting conditions adverse to quality in a continuing process of self-improvement.

1.1.2.E Ensuring personnel have adequate training to ensure competence commensurate with responsibility.

1.1.3 The QA program is binding on all project personnel, including those responsible for planning and scheduling activities and external organizations that implement the WTP Quality Assurance Program as specified by procurement documents. Management will ensure, through a formal, documented indoctrination and training program, that project personnel understand the basic QA program. Additional, in-depth training will be provided as appropriate to meet project-specific needs.

1.1.4 QA program implementation and maintenance will be verified through a two-tiered field assessment program. The first tier consists of on-going management assessments, described in Policy Q-18.3 – *Management Assessment,* that are performed by all levels of management to determine the level of program compliance, promote continuous improvement, and enhance project performance. The second tier consists of ongoing independent audits and surveillances performed by the QA organization in accordance with Policies Q-18.1 - *Independent Assessment (Audit)* and Q-18.2 - *Independent Assessment Surveillance*, to verify program implementation, maintenance, and the effectiveness of the management assessment process.

1.1.5 The QA program is the management system that addresses the major elements of the U.S. Department of Energy (DOE) QA Order (DOE-O 414.1B) and the Nuclear Quality

**Policy Q-02.1 Quality Assurance Program**

Assurance Rule (10 CFR 830, Subpart A): managing, performing, and assessing the adequacy of work. The QA program includes the QA Manual, (hereafter referred to as the manual) any special QA plans, the implementing procedures, and other documents. The QA Manual serves as the "umbrella" for defining the QA program. Additional QA plans, in the form of Quality Assurance plans, may be required and developed for specific project activities.

1.1.6 Quality Assurance Project Plans (QAPjPs) are written to address how Washington Administrative Codes or Environmental Protection Agency requirements are applied to project operations.

1.1.7 Quality Assurance Plans may be used to apply consensus standards in lieu of NQA-1 with prior DOE approval.

1.1.8 The QA Manual is structured to capture and integrate into a single cohesive QA program, the requirements that apply to the project as stated in the Contract (DE-AC27-01RV14136) and reflects the 18 criteria structure of NQA-1-1989 and DOE/RW-0333P, Revision 13. Each of the 18-plus policies that comprise the manual reflects the NQA-1 criteria structure. The policies, as appropriate, contain purpose and applicability statements, implementation strategy, discrete requirements or policy, and responsibilities of management and personnel for effective implementation of requirements. The QA Manager is responsible for the resources for developing and maintaining the manual. The Project Director retains the responsibility for authorizing the manual and assuring that the authority and independence of the QA Manager is such that he can effectively assure the conformance to quality requirements.

1.1.9 The implementation strategy and policy are two important elements that comprise each policy used in constructing the manual. The implementation strategy element is structured to describe appropriate methods and guidance for implementing the policy requirements to achieve implementation of a quality assurance program that surpasses minimum requirements and promotes project excellence. The policy element defines the contract requirements based on comparisons that have been made between the two major QA requirement documents that define operation of the project at large: NQA-1-1989 and DOE/RW-0333P, Revision 13, including the required supplements of each. Where requirements are equivalent, one statement has been selected as the requirement for the project. Where requirements are not equivalent, separate requirements are established and their applicability specified (i.e., applicable to the project at large or limited to Immobilized High Level Waste [IHLW] applications).

1.1.10 Requirements of this manual are to be contained in project procedures. These procedures can be supplemented by other lower-tier instructions and other implementing documents, where applicable, to provide the detail necessary for proper flowdown and implementation of QA requirements. The QA program documentation constitutes a significant portion of the project's Integrated Safety Management System (ISMS), which ensures that work is performed safely and in compliance with requirements. Current implementing documents can be found in the Quality Assurance Provisions Document (24590-WTP-QPD-QA-01-001). Documents will be added, deleted, or modified as necessary to reflect the requirements stated in this manual.

## 1.2 Quality Assurance Scope

1.2.1 The scope of the manual includes, but is not limited to, items and activities related to safe plant operation, and protection of personnel and the public. To ensure consistency in identifying quality-affecting items and activities, a classification process has been developed and is controlled through engineering procedures. This QA manual shall be applied to items and activities as described below:

1.2.1.A The program applies to radiological and nuclear process safety items and activities.

1.2.1.B This program applies to items and activities that affect product quality of the Immobilized Low-Activity Waste (ILAW), including but not limited to, entrained solids, waste form development, qualification, characterization, production process control, and certification. Research and technology activities used for waste form development, qualification, production, and acceptance shall be conducted in accordance with this policy as appropriate to the importance to safety and quality impact.

1.2.1.C This program applies to items and activities that affect the IHLW product quality, including but not limited to, waste form development, qualification, characterization, production process control, and certification. IHLW research and technology activities used for waste form development, qualification, production, and acceptance shall also be conducted in accordance with this manual.

1.2.1.D Permitting activities shall be conducted in accordance with the applicable requirements of this manual and all applicable laws and regulations.

1.2.1.E The requirements of this manual shall be applied, using the graded approach, to other project items and activities, including balance of facilities and pretreatment activities, based on their importance to safety and quality.

## 1.3 Items

1.3.1 Items to which this manual applies are designated as Q. The classification process for items is controlled through engineering procedures. This classification process produces an items list, which identifies the permanent plant structures, systems, and components that are within the scope of this manual and their specific classifications.

1.3.2 The classification of parts, materials, and consumable items and the technical and quality requirements shall be specified, documented, and approved as part of the engineering process.

1.3.3 Items affecting ILAW and IHLW shall be designated as such in accordance with engineering procedures.

## 1.4 Graded Approach

1.4.1 The scope, depth, and rigor of the application of quality assurance requirements to a specific item or activity should be determined by the use of a grading process. The

purpose of grading is to select the controls and verifications to be applied to various items and activities consistent with their importance to safety, cost, schedule, and success of the project. Grading is encouraged if a single or uniform method of applying a requirement across an item or activity does not add value or reduce risk. The grading process provides the flexibility to design controls that best suit the item or activity. The grading process is not used to obtain exemptions from the requirements of this manual.

1.4.2 The extent to which the requirements of this manual and its implementing documents are applied to an item or activity shall be based upon the following:

1.4.2.A Function or end use of the item.

1.4.2.B Consequence of failure (risk) of the item.

1.4.2.C Importance of the data being collected or analyzed.

1.4.2.D Complexity of design or fabrication of the item or design or implementation of the activity.

1.4.2.E Reliability of the process.

1.4.2.F Reproducibility of the results.

1.4.2.G Uniqueness of the item or degree of standardization.

1.4.2.H History of the item or service quality.

1.4.2.I Necessity for special controls or processes.

1.4.2.J Degree to which functional compliance can be demonstrated through inspection or test.

1.4.2.K Any other relevant factor.

1.4.3 The extent to which the requirements of this policy apply to an item shall be based on an evaluation of the above factors as well as other regulatory commitments as may have been made associated with the item. Such other plans or regulatory commitments include, but are not limited to, those associated with emergency planning, physical plant security, safeguard contingency planning, radiological controls, environmental controls, fire protection, in-service inspection, in-service testing, operator qualification and re-qualification, process control, and offsite dose calculation.

1.4.4 The varying degrees of the controls applied should be dependent upon function, complexity, consequence of failure, reliability, repeatability of results, and economic considerations. Risk is a fundamental consideration in determining to what extent controls should be applied. Risk is a quantitative or qualitative expression of possible impacts or loss (e.g., project, financial, safety) that considers both the probability of an event causing harm or loss and the consequences of the event. Determination (or estimation) of the probability or likelihood of the occurrence should be a part of the risk

expression. For example, procurement of Q items would require more rigorous supplier controls to meet procurement requirements than that needed for facility area lighting fixtures. Estimates and qualitative expressions are useful for management issues where quantitative data is unavailable. Process systems, repetitive activities, and hardware are typically suitable for quantitative expressions of risk.

1.4.5 Application of the graded approach shall be accomplished in accordance with procedures concurred with by the QA organization. The procedures shall include the provision to ensure that the application of the graded approach is consistently applied. Application of quality requirements to items shall be the responsibility of the Manager of Engineering.

## 1.5 Work Planning

1.5.1 Work planning ensures work is accomplished under suitably controlled conditions, and is a fundamental concept of Integrated Safety Management. Planning elements shall include, as appropriate:

1.5.1.A Definition of the work scope, objectives, and a listing of the primary tasks involved.

1.5.1.B Identification of changes in item form, fit, or function that would necessitate completion of an engineering design change prior to proceeding with the work.

1.5.1.C Identification of scientific approach or technical methods used to collect, analyze, or study results of applicable work.

1.5.1.D Identification of applicable standards and criteria.

1.5.1.E Identification and application, or development, of appropriate implementing documents.

1.5.1.F Identification of field and laboratory testing equipment or other equipment.

1.5.1.G Identification of appropriate measuring and test equipment.

1.5.1.H Identification of, or provisions for the identification of required records and the recording of objective evidence of the results of the work performed.

1.5.1.I Identification of QA program verifications of the work performed.

1.5.1.J Identification of prerequisites, special controls, environmental conditions, processes, or skills.

1.5.1.K Identification of computer software.

1.5.1.L Identification of applicable hazards, hazard mitigation, and the incorporation of applicable and relevant feedback to improve the work process and work activity.

1.5.1.M Identification of applicable housekeeping measures.

1.5.1.N Identification of appropriate controls for the exclusion of foreign materials from enclosed systems.

1.5.1.O Identification of appropriate controls for post-maintenance and post modification testing.

## 1.6 Control of the Quality Assurance Program

1.6.1 Revisions to the manual previously accepted by the DOE shall be concurred with by affected Senior Management and approved by the QA Manager. Revisions do not require approval by the DOE prior to issuance, but must be submitted to the DOE at least annually in accordance with the requirements of Section 830.121(b)(3) of 10 CFR Part 830, Subpart A, *"Quality Assurance Requirements."* The submittal of a revision to the manual shall include a justification for why the changes continue to satisfy the quality assurance requirements. Changes made to correct spelling, punctuation, or other editorial items do not require explanation. Such revisions shall be submitted to the DOE for approval and regarded as approved 90 days after submittal, unless it is approved or rejected by the DOE at an earlier date. The QA Manager shall approve all revisions to this manual.

## 1.7 Effective Date of Implementation

1.7.1 Changes to implementing procedures resulting from changes to this manual shall be incorporated within 90 days of the manual change approval date unless an interim action plan is defined and approved by the QA Manager.

## 1.8 Regulatory Commitments

1.8.1 The Environmental, and Nuclear Safety (E&NS) Manager is responsible for providing the BNI positions and interpretations on the regulatory documents to which BNI is committed. Changes to these commitments shall be accomplished in accordance with regulatory requirements. The QA Manager shall concur with changes to the positions and interpretations affecting this QA Manual.

## 1.9 Quality Assurance Program Review

1.9.1 The effectiveness of the QA program and its implementation is periodically reviewed at the department level and the results of these reviews are documented in reports to the Project Director and Senior Management for evaluation and corrective action as required. The effectiveness of the QA program is also evaluated and reported by the QA organization through the inspection, review, monitoring, auditing, and assessment functions. In addition, the QA organization at a minimum, annually, prepares evaluation reports on program effectiveness.

1.9.2 In addition to the reviews and evaluations performed above, the Project Director shall have an independent assessment of the QA program implementation performed at least annually. This assessment may be performed utilizing an independent consultant, representatives from other DOE locations, corporate representatives and/or senior staff

representatives. Any corrective action which may be deemed necessary as a result of these assessments shall be formally identified and tracked through resolution.

## 1.10 Quality Classification Process

1.10.1 The quality classification process for items and activities within the scope of the QA program shall be established using approved engineering procedures concurred with by QA. Systems and components shall be identified as either Q or CM in accordance with procedures. Subsection 1.4 provides the basis for grading which is the extent of application of the requirements of this policy.

## 1.11 External Organizations

1.11.1 Suppliers who provide items, parts, materials, consumables, and/or services that are within the scope of this program shall perform work to an appropriate QA program and implementing procedures. The supplier's QA program shall be subject to review and concurrence by QA. The extent to which the supplier's QA program shall be applied shall be specified by procurement documents.

## 1.12 Resolution of Differences and Escalations

1.12.1 Differences of opinion involving QA program requirements shall, if possible, be resolved at the level at which they occur. If this is not possible, the differences shall be escalated through supervisory/management levels until resolution is achieved.

1.12.2 The QA Manager, or if deemed necessary, the BNI Corporate QA Manager, shall be the arbiter on matters concerning the applicability and interpretation of the manual.

## 1.13 Integrated Safety Management System

1.13.1 Effective implementation of the QA requirements will also provide processes and tools to support principles and functions of the Safety Management System Policy (DOE P 450.4) and related portions of the DOE Acquisition Regulation (DEAR, 48 CFR 970.5204-2). The DOE Safety Management System Policy expresses a fundamental expectation that all work be performed safely. Project management's fundamental quality assurance expectation is that all work meets established requirements. In this regard, management ensures compliance with the approved standards set, so that the expectation for safe work within controls is met. This also ensures workers, the environment, and the public are reasonably protected from harm. The project's quality and safety requirements share a management systems approach to achieving their objectives. As such, compliance to established processes (e.g., procedures and instructions) satisfies quality and safety requirements.

1.13.2 Shared attributes of Quality and Safety Management Systems include:

1.13.2.A Expectations for implementation (DEAR 970.5204-2 (c)).

1.13.2.B Documentation of the Management System (ISMS Principle 7).

1.13.2.C Clear roles and responsibilities (ISMS Principle 2).

1.13.2.D Balanced priorities (resources) (ISMS Principle 4).

1.13.2.E Feedback and improvement (ISMS Core Function 5).

1.13.2.F Line management responsibility (ISMS Principle 1).

1.13.2.G Competence and qualifications (ISMS Principle 3).

1.13.2.H Standards and controls for work (ISMS Principle 5 and Core Function 4).

1.13.2.I Graded and tailored controls (ISMS Principle 6).

## 1.14 Flowdown of QA Program Requirements

1.14.1 In accordance with the principles of Integrated Safety Management, requirements must flow from their source down into working level documents. The project QA program applies, with appropriate grading of controls to the scope of work defined in BNI's contract with DOE, and is implemented through a variety of documents. This QA Manual serves to reflect the quality assurance requirements imposed by regulation and by contract (DE-AC27-01RV14136) and to provide the basis for their flowdown and implementation via implementing level documents. The following figure illustrates the requirements flow down from the various requirement sources to the implementing level documents.

## Requirements Flow To Work Processes

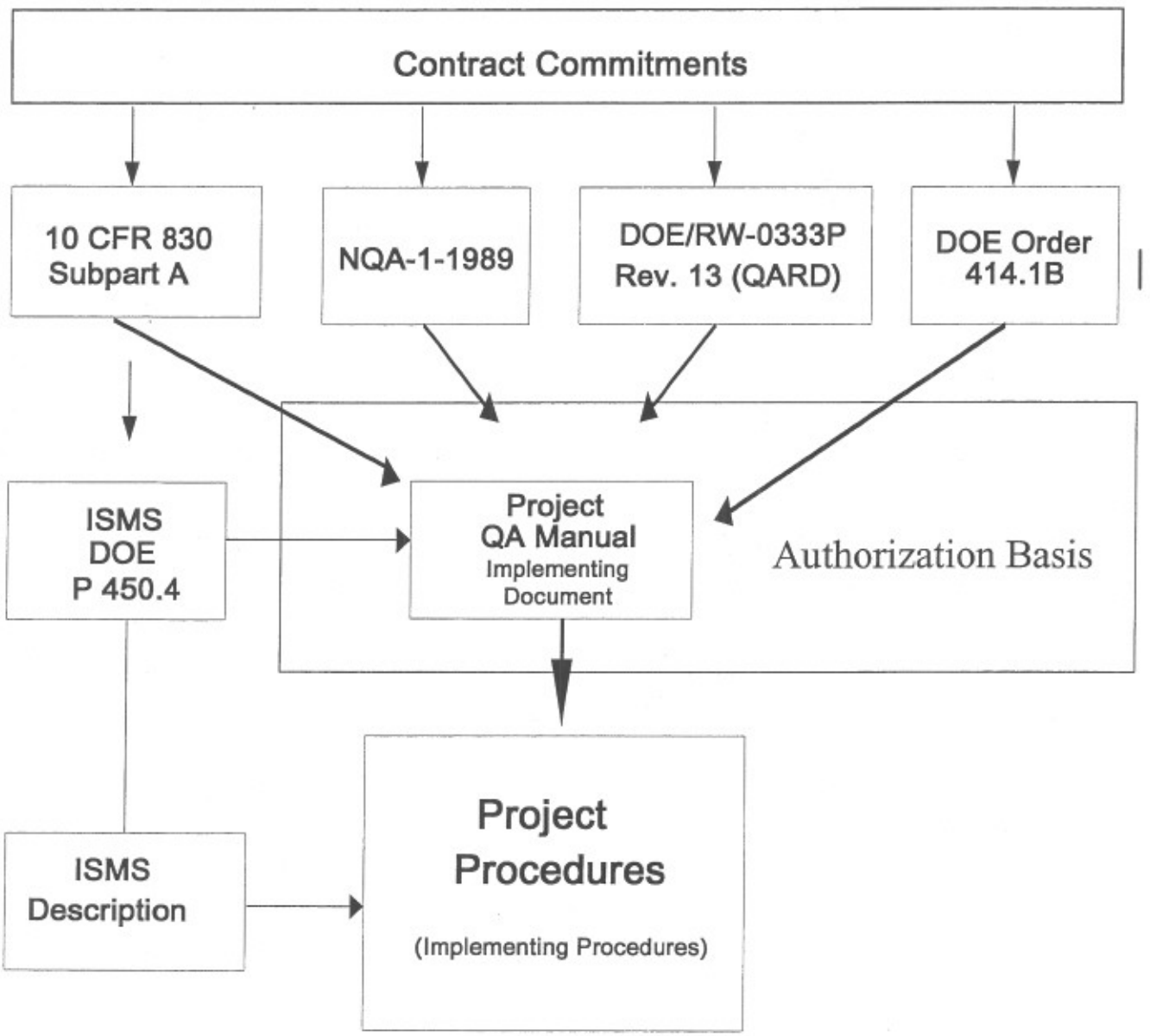



**Figure 2**
QA Program Requirements Flowdown

# Policy Q-02.2 Personnel Training and Qualification

## 1 Purpose and Applicability

1.1 This policy identifies responsibilities and requirements for the indoctrination, training, and qualification of personnel performing or managing activities affecting quality. It includes requirements for the training or indoctrination of personnel as to the technical objectives and requirements of the applicable codes and standards, and the applicable quality assurance requirements to be used on the project, and to ensure that appropriate continuing training is provided to maintain proficiency.

1.2 This policy applies to organizations and personnel performing activities that affect quality.

## 2 Implementation Strategy

2.1 In accordance with a guiding principle inherent in the core functions of Integrated Safety Management System (ISMS), project personnel will be trained and qualified commensurate with their responsibilities. Management will establish initial and continuing training and qualification requirements and processes for specific job categories. This ensures that personnel achieve the required competency commensurate with their responsibilities in accordance with the quality assurance (QA) program and the guiding principles of the ISMS.

2.2 The qualification of personnel performing activities affecting quality will be accomplished by consideration of experience, education, training, and may include demonstration and testing. Training programs are to consist of a combination of classroom, and on-the-job training, and/or include other training as it applies to the position. Classroom training includes lectures, seminars, computer-based training, and structured self-study activities.

2.3 All training and qualification programs for the project will be developed and implemented in a manner consistent with the hazards and the risks associated with the activity performed. Initial training programs will be established for personnel for indoctrination on project-specific requirements. These programs will be structured commensurate with specific position needs. Examinations and/or operational evaluations on material included in the training programs are to be administered and documented as appropriate. Each organization is responsible for training and qualification of their personnel. Organizational interfaces with the training organization will be addressed in implementing procedures. The role of the training organization will be defined in project procedures that include training program scope commensurate with personnel responsibilities.

2.4 Continuing training will be established to maintain and enhance the knowledge and skills of personnel commensurate with specific position needs. Continuing training will include, as applicable, training in significant applicable procedure changes, applicable industry operating experience, selected fundamentals with emphasis on knowledge and skills necessary to assure safety, and other training as needed to correct identified performance problems.

2.5 Training and qualification procedures will establish processes that are used by project personnel for the conduct of training and qualification programs. Training profiles or plans are to be designed both to prepare individuals to perform a job and to maintain performance

while in a job. Training profiles or plans may also be used to identify improvement opportunities for those in a job.

2.6 Instructors should engage in performance-based training and be appropriately qualified for the specific training tasks. Classroom instructors will be qualified by the appropriate project training organization. Instructor training should be based, in part, on the results of instructor evaluations and the need for training on new methods and equipment. Classroom instructors should possess the technical knowledge, experience, and development and instructional skills commensurate with the subject material and the level of instruction.

2.7 Procedures implementing the Personnel Training and Qualification requirements of this policy shall provide for developing worker competence commensurate with the scope, complexity, and nature of the activities their jobs require. Personnel training and qualification shall be conducted utilizing approved procedures that implement the requirements of this policy.

# 3 Policy

## 3.1 General

3.1.1 Each organization shall provide for indoctrination, training, and formal qualification, as necessary, of personnel performing or managing activities affecting quality to assure that suitable proficiency is achieved and maintained.

3.1.2 Management may delegate formal qualification examination activities to an independent certifying agency, but shall retain responsibility for the examination and its administration.

## 3.2 Indoctrination and Training

3.2.1 Indoctrination and training shall be commensurate with the scope, complexity, and importance of the activities, and the education, experience, and proficiency of the personnel.

3.2.2 Personnel performing or managing activities affecting quality shall receive indoctrination in their job responsibilities and authority, general criteria, including applicable codes and standards, company procedures, and quality assurance program requirements, before performing quality-affecting work.

3.2.3 The need for a formal training program for personnel performing or managing activities affecting quality shall be determined. Training shall be provided, if needed, to achieve initial proficiency, maintain proficiency, and adapt to changes in technology, methods, or job responsibilities.

## 3.3 Formal Qualification Requirements

3.3.1 The responsible organization shall designate those activities that require formal qualification of personnel and the minimum requirements for such personnel.

**Policy Q-02.2 Personnel Training and Qualification**

3.3.2 The responsible organization shall establish written procedures for the formal qualification of personnel, and for the assurance that only those personnel who meet the requirements are permitted to perform the activities identified in 3.3.1.

3.3.3 Qualification requirements for personnel performing nondestructive examination (NDE), inspection and tests to verify quality, are as follows:

3.3.3.A Personnel who perform NDE including radiographic, magnetic particle, ultrasonic, liquid penetrant, electromagnetic, neutron radiography, leak testing, and acoustic emission, to verify conformance to specified requirements shall be qualified to procedures that meet the requirements of any edition of the *American Society of Nondestructive Testing Recommended Practice* No. SNT-TC-1A, June 1980 Edition through 2001 Edition and its applicable supplements. In lieu of the three-year certification interval specified in SNT-TC-1A, June 1980 Edition, Level III Nondestructive Examination personnel may be recertified on a five-year interval. When required by the implementing code, visual testing will be subject to these same requirements.

3.3.3.B Inspection and test personnel qualification requirements will be included in specific procedures.

3.3.3.C Inspection and test personnel shall be qualified as required by specific procedures.

3.3.3.D The initial capabilities of an inspection and test candidate shall be determined by an evaluation of the candidate's education, experience, training, and either test results or capability demonstration.

3.3.3.E Re-evaluation of independent inspection and test personnel job performance shall be by evidence of continued satisfactory performance or redetermination of capability in accordance with the requirements of this policy. If, during this evaluation, or at any other time, it is determined by the responsible organization that the capabilities of an individual are not in accordance with the qualification requirements specified for the job, that person shall be removed from that activity until such time as the required capability has been demonstrated. Work performed by the individual during the time they were not qualified, shall be evaluated by a qualified individual for acceptance. The evaluation shall be documented.

3.3.3.F Any person who has not performed independent inspection or testing activities in the qualified area for a period of one year shall be re-evaluated.

3.3.4 Qualification/certification requirements for QA auditors/lead auditors and technical specialists shall be as identified in Policy Q-02.3 - *Auditor/Lead Auditor Qualification and Certification*.

## 3.4 Continuing Training

3.4.1 Continuing training will include, as applicable, training in significant applicable procedure changes, applicable industry operating experience, selected fundamentals with

emphasis on knowledge and skills necessary to assure safety, and other training as needed to correct identified performance problems.

# 4 Specific DOE/RW-0333P QARD Requirements for IHLW Applications

In addition to the requirements found in section 3 of this Policy, the following requirements are applicable to High Level Waste activities and shall be implemented.

4.1 For personnel who perform or manage design, scientific investigations, software development activities, and for personnel who verify or manage the verification of design, scientific investigation, software development activities, or items, affected organizations shall ensure that:

4.1.1 Descriptions are established for the positions these personnel occupy.

4.1.2 Minimum education and experience requirements are established for each position commensurate with the scope, complexity, and nature of the work.

4.1.3 Personnel have experience and education commensurate with the minimum requirements established. Documented justification is provided for persons that do not meet minimum education and experience requirements.

4.1.4 Minimum education and experience are verified or, when minimum education and experience cannot be verified, documented justification is provided for the personnel assignment.

# 5 Records

5.1 Qualification and training records shall be controlled in accordance with Policy Q-17.1 - *Quality Assurance Records*.

5.2 Records of personnel training and/or qualification for activities affecting quality shall be established and maintained by the project.

5.2.1 Note: Records of the implementation for indoctrination and training may take the form of attendance sheets, training logs, or personnel training records.

# 6 Responsibilities

## 6.1 All Managers

6.1.1 Are responsible for:

6.1.1.A Developing job specific training and minimum education and experience requirements.

6.1.1.B Establishing training requirements for project personnel.

6.1.1.C Committing resources to provide training to personnel performing activities that affect quality within their organizations.

6.1.1.D Ensuring that personnel within their organization comply with requirements for indoctrination, training, qualification, and that suitable proficiency is achieved and maintained.

6.1.1.E Reviewing job responsibilities and scope-of-work assignments to ensure that the training program is maintained current with work assignments and is updated to improve overall work performance.

6.1.1.F Ensuring indoctrination and training is completed prior to performing work.

6.1.1.G Ensuring that when work must be performed by an individual prior to completion of indoctrination and training, or completion of qualification requirements, the individual will be supervised and all work products will be reviewed and approved for use by a qualified individual.

## 6.2 The Operations Manager

6.2.1 Is responsible for:

6.2.1.A Training department activities and implementation, control, and maintenance of the training matrix for tracking training of personnel and for determining the status of the training program.

6.2.1.B Control and maintenance of training and certification records as required until turnover to the project records management system.

6.2.1.C Issuing and controlling implementing procedures for the training and indoctrination process.

## 6.3 The Manager of Construction

6.3.1 Is responsible for:

6.3.1.A Construction training activities and implementation, control, and maintenance of the training database for tracking training of construction personnel and for determining the status of their training.

6.3.1.B Control and maintenance of construction-related training and certification records as required until turnover to the project records management system.

## 6.4 The Business Services Manager

6.4.1 Is responsible for:

6.4.1.A Providing support for the hiring of qualified personnel to meet position requirements, when required.

6.4.1.B Documenting and providing evidence of education and experience as required by the position description.

## 6.5 The Quality Assurance Manager

6.5.1 Is responsible for:

6.5.1.A Periodically assessing the status and effectiveness of the indoctrination and training programs to ensure that they continue to reflect the current systems, procedures, and policies applicable to each position. Assessments of the training program conducted by the QA Manager shall be coordinated with the Project Manager and shall be scheduled and conducted at least annually.

6.5.1.B Control and maintenance of QA training and certification records as required until turnover to the project records management system.

## 6.6 All Personnel

6.6.1 Are responsible for:

6.6.1.A Complying with the indoctrination, training, and qualification requirements applicable to their job assignment, and maintaining their job proficiency.

# Policy Q-02.3 Auditor/Lead Auditor Qualification and Certification

## 1 Purpose and Applicability

1.1 This policy identifies responsibilities and requirements for the qualification and certification of quality assurance (QA) auditors and lead auditors. It includes requirements for the initial and continuing qualification and/or certification of technical specialists, auditors, and lead auditors.

1.2 This policy applies to the QA organization and other organizations supporting quality assurance audits.

## 2 Implementation Strategy

2.1 In accordance with a guiding principle inherent in all of the core functions of the Integrated Safety Management System (ISMS), personnel conducting QA auditing activities will be trained and qualified commensurate with their responsibilities to ensure they are capable of performing their assigned work. The QA manager will establish the training and qualification requirements for technical specialists, auditors, and lead auditors. This ensures that personnel achieve the required competency commensurate with their responsibilities in accordance with the QA program and the guiding principles of the ISMS.

2.2 The qualification of auditing personnel will be accomplished by consideration of experience, education, training, and by demonstration and testing, as applicable, to verify acquired skills. Auditor and lead auditor training normally will consist of a combination of general and specialized training in audit performance, including general training in auditing fundamentals such as objectives, characteristics, organization, performance, and reporting results of quality auditing; and the specialized training shall include methods of examining, questioning, evaluating, and documenting specific audit items and methods of closing out audit findings.

2.3 Training and qualification procedures will establish the methodology for auditor and lead auditor training and qualification programs. Training profiles or plans are to be designed both to prepare individuals to perform auditing activities and to maintain performance.

2.4 Procedures implementing the auditor and lead auditor qualification requirements of this policy shall provide for developing and maintaining auditor proficiency commensurate with the scope, complexity, and nature of the activities their jobs require. Auditor and lead auditor training and qualification shall be conducted utilizing approved procedures that implement the requirements of this policy.

## 3 Policy

### 3.1 General

3.1.1 Auditors and lead auditors shall be trained, qualified, and lead auditors shall be certified in accordance with the requirements of this policy and Policy Q-02.2 - *Personnel Training and Qualification*.

**Policy Q-02.3 Auditor/Lead Auditor Qualification and Certification**

3.1.2 Personnel selected for quality assurance auditing assignment shall have experience or training commensurate with the scope, complexity or special nature of the activities to be audited.

3.1.3 Management may delegate formal qualification examination activities to an independent certifying agency, but shall retain responsibility for the examination and its administration.

## 3.2 Auditor Qualifications

3.2.1 Auditors shall have, or be given, appropriate training or orientation to develop their competence for performing audits.

3.2.2 Competence of personnel for performing the various auditing functions shall be developed by one or more of the following methods:

3.2.2.A Orientation to provide a working knowledge and understanding of the QA program requirements, and the auditing organization's procedures for performing audits and reporting results.

3.2.2.B General and specialized training in audit performance, where the general training shall include auditing fundamentals such as objectives, characteristics, organization, performance, and reporting results of quality auditing; and the specialized training shall include methods of examining, questioning, evaluating, and documenting specific audit items and methods of closing out audit findings.

3.2.2.C On-the-job training, guidance, and counseling under the direct supervision of a lead auditor. Such training shall include planning, performing, reporting, and follow-up action involved in conducting audits.

## 3.3 Lead Auditor Qualifications and Certifications

3.3.1 A lead auditor shall be capable of organizing and directing audits, reporting audit findings, and evaluating planned and taken corrective actions. An individual shall meet the following requirements prior to being designated as a lead auditor.

3.3.2 Communication Skills

3.3.2.A The prospective lead auditor shall be capable of effective written and oral communication. These skills shall be attested to in writing by the lead auditor's manager.

3.3.3 Training

3.3.3.A Prospective lead auditors shall receive training to the extent necessary to assure auditing competence including:

3.3.3.A.1. Knowledge and understanding of requirement documents and other nuclear-related codes, standards, regulations, and regulatory guides, as applicable.

**Policy Q-02.3 Auditor/Lead Auditor Qualification and Certification**

3.3.3.A.2. General structure of QA programs as a whole, and applicable elements as defined in requirement documents.

3.3.3.A.3. Auditing techniques of examining, questioning, evaluating, and reporting, methods of identifying and following up on corrective action items, and closing out audit findings.

3.3.3.A.4. Planning audits of activities affecting quality.

3.3.3.A.5. On-the-job training to include applicable elements of the audit program.

3.3.4 Audit Participation

3.3.4.A Prospective lead auditors shall participate in a minimum of five quality assurance audits within a period of time not to exceed three years prior to the date of qualification and certification, one audit of which shall be a nuclear quality assurance audit within the year prior to qualification and certification.

3.3.5 Examination

3.3.5.A Prospective lead auditors shall pass an examination, which shall evaluate comprehension of and ability to apply the body of knowledge identified above. The examination may be oral, written, practical, or any combination thereof.

3.3.5.B The development and administration of the examination for a lead auditor is the responsibility of the auditing organization. The auditing organization shall develop and maintain objective evidence regarding the type, content, and results of the examination.

3.3.6 Maintenance of Proficiency

3.3.6.A Lead auditors shall maintain their proficiency through one or more of the following: regular and active participation in the audit process; review and study of codes, standards, procedures, instructions, and other documents related to the QA program and program auditing; or participation in QA training program(s).

3.3.6.B Management of the auditing organization shall evaluate the proficiency of lead auditors annually. Management evaluations shall be documented.

3.3.6.B.1. Note: Based on annual assessment, management may extend the qualification, require re-training, or require re-qualification.

3.3.7 Re-Qualification

3.3.7.A Lead auditors who fail to maintain their proficiency for a period of two years or more shall be required to re-qualify. Re-qualification shall include re-training in accordance with the requirements of subsection 3.3.3 of this policy, re-examination in accordance with the requirements of subsection 3.3.5 of this policy, and participation as an auditor in at least one nuclear quality assurance audit.

**Policy Q-02.3 Auditor/Lead Auditor Qualification and Certification**

3.3.8 Certification of Qualification

3.3.8.A Each lead auditor shall be certified by the auditing organization as being qualified to lead audits.

3.3.8.B The qualification of lead auditor personnel shall be certified in writing and shall document the following information:

3.3.8.B.1. Employer's name.

3.3.8.B.2. Identification of person being certified.

3.3.8.B.3. Activities certified to perform.

3.3.8.B.4. Basis of qualification to include:

3.3.8.B.4.1. Education, experience, indoctrination, and training.

3.3.8.B.4.2. Test results, where applicable.

3.3.8.B.4.3. Capability demonstration results.

3.3.8.B.5. Results of periodic evaluation.

3.3.8.B.6. Results of physical examinations, when required.

3.3.8.B.7. Signature of employer's designated representative responsible for such certification.

3.3.8.B.8. Date of certification or re-certification and certification expiration.

3.3.8.C The responsible organization shall identify any special physical characteristics needed in the performance of each activity, including the need for initial and subsequent physical examination.

3.3.8.D The auditing organization shall maintain the integrity of the examination through confidentiality of files and, where applicable, proctoring of examinations. Copies of the objective evidence regarding the type(s) and content of the examination(s) shall be retained by the auditing organization in accordance with subsection 5.0 of this policy.

3.3.9 Qualification Credits Scoring Systems

3.3.10 The prospective lead auditor shall have verifiable evidence that a minimum of ten credits have been accumulated under the following scoring system:

3.3.10.A Education (four credits maximum):

3.3.10.A.1. An Associate's Degree from an accredited institution scores one credit; if the degree is in engineering, physical sciences, mathematics, or QA, it scores two credits.

3.3.10.A.2. A Bachelor's Degree from an accredited institution scores two credits; if the degree is in engineering, physical sciences, mathematics, or QA, it scores three credits.

3.3.10.A.3. In addition, score one credit for a Master's Degree in engineering, physical sciences, business management, or QA from an accredited institution.

3.3.10.B Experience (nine credits maximum) - Technical experience in such areas as scientific investigation, site characterization, production, transportation, engineering, manufacturing, construction, operation, maintenance, or experience applicable to the auditing organization's area of responsibility scores one credit for each full year, with a maximum of five credits for this aspect of experience:

3.3.10.B.1. If two years of this experience have been in the nuclear-related field, score one additional credit; or

3.3.10.B.2. If two years of this experience have been in QA, score two additional credits; or

3.3.10.B.3. If two years of this experience have been in auditing, score three additional credits; or

3.3.10.B.4. If two years of this experience have been in nuclear-related QA, score three additional credits; or

3.3.10.B.5. If two years of this experience have been in nuclear-related QA auditing, score four additional credits.

3.3.10.C Professional Competence (two credits maximum) - For certification of competency in engineering science or QA specialties issued and approved by a state agency or national professional or technical society, score two credits.

3.3.10.D Rights of Management (two credits maximum) - When determined appropriate, the auditing organization may grant up to two credits for other performance factors applicable to auditing that are not explicitly called out in this section (such as leadership, sound judgment, maturity, analytical ability, tenacity, past performance, and completed QA training courses).

## 3.4 Technical Specialist Training

3.4.1 Personnel shall be indoctrinated and trained to achieve initial proficiency prior to performing or participating in audits. Initial proficiency includes familiarization with the Quality Assurance Manual and its implementing procedures related to auditing and auditing qualifications.

3.4.2 Technical specialists shall have the level and experience or training commensurate with the scope, complexity, or special nature of the work being audited.

# 4 Specific DOE/RW-0333P QARD Requirements for IHLW Applications

4.1 All applicable DOE/RW-0333P QARD requirements have been included in subsection 3 – *Policy*.

# 5 Records

5.1 All records shall be controlled in accordance with Policy Q-17.1 – *Quality Assurance Records*.

5.2 Records of personnel qualification, including re-qualification for auditors and lead auditors performing audits, shall be established and maintained by the project.

# 6 Responsibilities

6.1 Quality Assurance Manager

6.1.1 The QA Manager is responsible for the following:

6.1.1.A Defining the requirements for technical specialist, auditor, and lead auditor qualification and certification.

6.1.1.B Evaluating objective evidence to determine acceptability for auditor/lead auditor qualification against criteria in this policy.

6.1.1.C Qualifying auditors and lead auditors, and certifying lead auditors.

6.1.1.D Providing for auditor/lead auditor training.

6.1.1.E Providing for an examination of prospective lead auditors.

6.1.1.F Ensuring that records of auditor/lead auditor qualification are established and maintained.

## 6.2 Quality Assurance Assessment Manager

6.2.1 The Quality Assurance Assessment Manager is responsible for submitting documentation of a prospective auditor's/lead auditor's work history/experience to the QA Manager.

## 6.3 Lead Auditors

6.3.1 Lead Auditors are responsible for counseling and/or evaluating prospective auditors/lead auditors and documenting their proficiency.

# Policy Q-02.4 Special Reviews

## 1 Purpose and Applicability

1.1 This policy identifies additional requirements from the Quality Assurance Requirements Document (QARD) (DOE/RW-0333P), Revision 13, which are specific to the project for ensuring that readiness and peer reviews are identified, planned, and implemented where needed.

1.2 This policy applies to project organizations performing readiness and peer reviews.

## 2 Implementing Strategy

2.1 Peer reviews are conducted for work that the adequacy of information or the suitability of implementing documents and methods to meet specified objectives cannot be established through testing, alternate calculations, or reference to previously established standards or practices. Peer reviews are performed by one or more individuals who have technical expertise collectively at least equivalent to those who performed the original work. The peer review is an in-depth critique of assumptions, documents, calculations, extrapolations, alternative interpretations, methodology acceptance criteria, conclusions, and material or data that require interpretation or judgement to verify or validate them.

2.2 Requirements for Operational Readiness Reviews (ORR) are also to be established and documented. When required by the established criteria, an ORR will be performed prior to major scheduled or planned facility restarts. ORRs are to be performed at the request of the management responsible for the activity under review to ensure a technically competent assessment.

2.3 ORRs will be independent of other management activities to the extent necessary to provide an unbiased perspective. ORRs will include, as a minimum, verification of the following characteristics:

2.3.1 Work prerequisites are satisfied.

2.3.2 Detailed technical and quality assurance (QA) procedures, applicable to the work to be performed, are reviewed for adequacy and appropriateness.

2.3.3 Personnel are suitably trained and qualified.

2.3.4 Proper equipment, material, and resources are available.

2.4 Peer reviews and ORRs are part of the feedback and improvement function of the Integrated Safety Management System (ISMS).

2.5 The Manager of Engineering and Operations Manager are responsible for developing the implementing procedures for conducting peer reviews and operational readiness reviews that are concurred with by the QA organization that contain the requirements of this policy.

**Policy Q-02.4 Special Reviews**

# 3 Policy

## 3.1 Readiness Reviews

3.1.1 Line management shall plan, schedule, and conduct readiness reviews at significant transitional events both leading up to and during waste form production.

3.1.2 The need for readiness reviews shall be identified by affected organization management for major scheduled or planned work to ensure program objectives are met.

3.1.3 Where needed, readiness reviews shall be conducted for the planned scope of work to ensure that objective evidence exists demonstrating that:

3.1.3.A Work prerequisites have been satisfied.

3.1.3.B Personnel have been suitably trained and qualified.

3.1.3.C Detailed implementing documents and management controls are available and approved.

## 3.2 Peer Reviews

3.2.1 Peer reviews shall be conducted when the adequacy of information or the suitability of implementing documents and methods essential to meet specified objectives cannot be established through testing, alternate calculations, or reference to previously established standards and practices.

3.2.2 The following conditions are situations for which a peer review shall be considered:

3.2.2.A Critical interpretations or decisions will be made in the face of significant uncertainty, including the planning for data collection, research, or exploratory testing.

3.2.2.B Decisions or interpretations having significant impact on performance assessment results will be made.

3.2.2.C Novel or beyond the state-of-the-art testing, plans and procedures, or analyses will be utilized.

3.2.2.D Detailed technical criteria or standard industry procedures are not available.

3.2.2.E Results of tests are not reproducible or repeatable.

3.2.2.F Data or interpretations are ambiguous.

3.2.2.G Data adequacy is questionable (e.g., the data may not have been collected in conformance with an established QA program).

**Policy Q-02.4 Special Reviews**

3.2.3 Management shall determine the need for and, as appropriate, shall initiate peer reviews when the adequacy of a critical body of information can be established by alternate means, but there is significant disagreement regarding the applicability or appropriateness of the alternate means. In conducting a peer review, management shall ensure that the:

3.2.3.A Number of the peer reviewers is commensurate with the complexity of work to be reviewed, its importance to project objectives, the number of technical disciplines involved, the degree to which uncertainties in the data or technical approach exist, and the extent to which differing viewpoints are strongly held within the applicable technical and scientific community concerning issues under review.

3.2.3.B Collective technical expertise and qualifications of the peer reviewers span the technical issues and areas involved in the work to be reviewed, including differing bodies of scientific thought.

3.2.3.C Technical areas central to the work to be reviewed receive appropriate proportional representation among the peer reviewers.

3.2.3.D Potential for technical or organizational partiality is minimized.

3.2.3.E Peer review group chairperson is identified.

3.2.4 Peer reviews shall be performed by individuals that have:

3.2.4.A Technical qualifications in the review area at least equivalent to that needed for the work under review.

3.2.4.B Technical credentials that are recognized and verifiable.

3.2.4.C Independence from the work under review. Independence means that the individual was not involved as a participant, supervisor, technical reviewer or advisor in the work under review and is, to the extent practical, free from any funding considerations.

3.2.4.C.1. Note: In those cases where total independence cannot be met, the rationale as to why someone of equivalent technical qualification and greater independence was not selected shall be documented in the peer review report.

3.2.5 Initiation of the peer review shall require the development of a planning document that:

3.2.5.A Specifies the work to be reviewed.

3.2.5.B Identifies the size and spectrum of the peer review group.

3.2.5.C Describes the expected method and reporting schedule.

3.2.5.D Establishes review criteria that shall include, as appropriate:

3.2.5.D.1. Validity of the assumptions.

3.2.5.D.2. Alternate interpretations.

3.2.5.D.3. Adequacy of requirements and criteria.

3.2.5.D.4. Appropriateness and limitations of the methods and implementing documents used to complete the work under review.

3.2.5.D.5. Adequacy of application.

3.2.5.D.6. Accuracy of calculations.

3.2.5.D.7. Validity of conclusions.

3.2.5.D.8. Uncertainty of results and impact if wrong.

3.2.6 The peer review chairperson shall provide a report that:

3.2.6.A Is signed by each peer reviewer or contains information detailing which peer reviewers have chosen not to sign and why.

3.2.6.B States the work or issue that was reviewed and the conclusions of the review.

3.2.6.C Includes individual statements by the peer reviewers reflecting dissenting views or additional comments, as appropriate.

3.2.6.D Includes a listing of the peer reviewers and a statement that the qualifications and experience of each reviewer have been evaluated and are acceptable.

# 4 Specific DOE/RW-0333P QARD Requirements for IHLW Applications

4.1 All applicable DOE/RW-0333P QARD requirements have been included in subsection 3 – *Policy*.

# 5 Records

5.1 The results of readiness reviews shall be documented and controlled in accordance with Policy Q-17.1 – *Quality Assurance Records*.

5.2 Final Reports issued by the peer review chairman shall be controlled in accordance with Policy Q-17.1 – *Quality Assurance Records*.

# 6 Responsibilities

## 6.1 Project Manager

6.1.1 The Project Manager is responsible for the following:

6.1.1.A Identifying the need for readiness reviews.

6.1.1.B Ensuring that readiness reviews are conducted in accordance with the requirements of this policy.

6.1.1.C Developing and approving the necessary implementing documents for conducting readiness reviews.

6.1.1.D Participating in peer reviews as required.

## 6.2 Manager of Engineering

6.2.1 The Manager of Engineering is responsible for the following:

6.2.1.A Identifying the need for and initiating peer reviews as appropriate.

6.2.1.B Ensuring that peer reviews are conducted in accordance with the requirements of this policy.

6.2.1.C Participating in readiness reviews as required.

## 6.3 Quality Assurance Manager

6.3.1 The QA Manager is responsible for reviewing and concurring with the procedures that implement the requirements of this policy and participating in readiness reviews as required.

# Policy Q-03.1 Design Control

## 1 Purpose and Applicability

1.1 This policy identifies requirements and responsibilities for ensuring that designs are defined, controlled, and verified.

1.2 This policy applies to quality-affecting design activities for the project.

## 2 Implementation Strategy

2.1 Design control processes are part of the Integrated Safety Management System (ISMS) core functions of Define Scope of Work, Analyze Hazards, and Develop/Implement Controls. Items and systems/processes will be designed using sound engineering/scientific principles, and appropriate standards. Engineering practices and procedures will be established and implemented to perform and control design, including design requirements, inputs, processes, outputs, changes, records, and organizational interfaces. Controls are to apply to software and experiments if part of the design process and consequential safety, environment, health, or programmatic risks are identified. The Manager of Engineering is responsible for ensuring that the graded approach for the application of appropriate design controls is performed commensurate with the quality levels as described in Policy Q-02.1 – *Quality Assurance Program* - subsection 1.10 - *Quality Classification.* Various elements of the quality assurance (QA) program and administrative controls will be applied in accordance with these quality levels throughout the life of the design. Design control measures will correctly translate appropriate codes, standards and quality requirements to ensure structures, systems, or components (SSC) meet their specified design requirements.

2.2 Design work, including changes, will incorporate applicable requirements and design bases. Design control procedure(s) specify design basis elements that must be considered during development of design input documents. Requirements for determining design bases include basic function and performance requirements; computer systems and applicable software programs; design and environmental conditions; material requirements; interface requirements; operational, maintenance, constructability, and redundancy requirements; and fire protection, safety, quality, and reliability requirements. Requirements are to typically be contained in functional performance requirements and functional design criteria documents.

2.3 Design control processes will ensure that design input requirements are correctly translated into design output documents, such as drawings and design/procurement specifications. Design input/output alignment, including drawings, calculations/analyses, computer codes, and supporting documentation, will be an integral part of the design verification process performed during various phases of design development to ensure that the applicable requirements are properly incorporated throughout the design activities.

2.4 The Manager of Engineering is responsible for developing and maintaining engineering procedures that identify design requirements and technical standards, and establishes engineering process, roles and responsibilities, and engineering personnel qualification requirements. Procedures are developed to implement engineering processes and meet the requirements of this policy. Designs shall be defined, controlled, and verified utilizing approved procedures concurred with by the quality assurance organization that implement the requirements of this policy.

# 3 Policy

## 3.1 General

3.1.1 The design shall be defined, controlled, and verified.

3.1.2 Design interfaces shall be identified and controlled.

3.1.3 Individuals other than those who designed the item or computer program shall verify design adequacy.

3.1.4 Design changes, including field changes, shall be governed by control measures commensurate with those applied to the original design.

3.1.5 Where appropriate, drawings, specifications, and other design output documents shall contain appropriate inspection and testing acceptance criteria.

3.1.6 Computer software used to perform design analyses shall be developed or qualified, and used according to the requirements of Policy Q-03.2 - *Software Control*.

## 3.2 Design Input

3.2.1 Applicable design inputs shall be identified and documented and their selection reviewed and approved by those responsible for the design.

3.2.2 The design input shall be specified and approved on a timely basis to the level of detail necessary to permit the design activities to be carried out in a correct manner and to provide a consistent basis for making design decisions, accomplishing design verification measures, and evaluating design changes.

3.2.3 Changes from approved design inputs and reasons for the changes shall be identified, approved, documented, and controlled.

3.2.4 Design inputs based on assumptions that require confirmation shall be identified and controlled as the design proceeds.

## 3.3 Interface Control

3.3.1 Design efforts shall be coordinated among participating organizations and groups.

3.3.2 Design information transmitted across interfaces shall be documented and controlled. The controls shall identify the status of the design information or document provided, and identify designs or portions of designs that require further development, analysis, review, or approval.

3.3.3 Where it is necessary to initially transmit design information orally or by other informal means, the transmittal shall be confirmed promptly by a controlled document.

3.3.4 Interface controls shall include the assignment of responsibility and the establishments of controls among participating organizations for the review, approval, release, distribution, and revision of documents involving design interfaces.

## 3.4 Design Process

3.4.1 The responsible design organization shall prescribe and document the design activities on a timely basis and to the level of detail necessary to permit the design process to be carried out in a correct manner and to permit verification that the design meets requirements.

3.4.2 Design documents shall adequately support facility design, construction, commissioning, and operation.

3.4.3 Appropriate standards shall be identified and documented, and their selection reviewed and approved. Changes from specified standards, including the reasons for the changes, shall be identified, approved, documented, and controlled.

3.4.4 The design methods, materials, parts, equipment, and processes that are essential to the function of the items shall be selected and reviewed for suitability of application.

3.4.5 Applicable information derived from experience, as set forth in reports or other documentation, shall be made available to cognizant design personnel.

3.4.6 The final design, including approved design output documents and approved changes shall:

3.4.6.A Relate to the design input through documentation in sufficient detail to permit design verification.

3.4.6.B Specify the minimum acceptance requirements.

3.4.6.C Identify assemblies and/or components that are part of the item being designed. When such an assembly or component part is a commercial grade item, characteristics of the item to be verified for acceptance and the acceptance criteria for those characteristics shall be documented.

3.4.7 The final design shall identify assemblies or components that are part of the item being designed. If a commercial grade item, prior to its installation, is modified or selected by special inspection and/or testing to requirements that are more restrictive than the supplier's published product description, the component part shall be represented as different from the commercial grade item in a manner traceable to a documented description of the difference.

## 3.5 Design Analyses

3.5.1 Design analyses shall be planned, controlled, and documented.

3.5.2 Design analyses shall be sufficiently detailed such that a person technically qualified in the subject can review and understand the analyses and verify the adequacy of the results without recourse to the originator.

3.5.3 Design analysis documents shall be legible and in a form suitable for reproduction, filing, and retrieval.

3.5.4 Calculations shall be controlled and identified by subject (including structure, system, or component to which the calculation applies), originator, reviewer, and date, or by other designators such that the calculations are retrievable.

3.5.5 Documentation of design analyses shall include:

3.5.5.A Definition of the objective of the analyses.

3.5.5.B Design inputs and their sources.

3.5.5.C Results of literature searches or other applicable background data.

3.5.5.D Identification of assumptions and those that must be verified as the design proceeds.

3.5.5.E Identification of any computer calculation, including: identification of the computer type, computer program name, and revision; inputs; outputs; evidence of or reference to computer program verification; and the basis (or reference thereto) supporting application of the computer program to the specific physical problem.

3.5.5.F Identification of the originator, reviewer, and approver.

3.5.6 To the extent required in subsection 3.5.7 of this policy, computer program acceptability shall be pre-verified or the results verified with the design analysis for each application. Pre-verified computer programs shall be controlled in accordance with the requirements of this policy.

3.5.7 The computer program shall be verified to show that it produces correct solutions for the encoded mathematical model within defined limits for each parameter employed. The encoded mathematical model shall be shown to produce a valid solution to the physical problem associated with the particular application.

## 3.6 Design Verification

3.6.1 Design verification shall be performed to determine the adequacy of the design. Acceptable verification methods include, but are not limited to, any one or a combination of design reviews, alternate calculations, and qualification testing.

3.6.2 The extent of the design verification shall be a function of the importance to safety, the complexity of the design, the degree of standardization, the state of the art, and the similarity with previously proved designs.

3.6.3 Design verification shall be performed prior to releasing the design for procurement, manufacture, construction, or release to another organization for other design activities except where this timing cannot be met, such as when insufficient data exist. In those cases, the unverified portion of the design shall be clearly identified and controlled. In all cases the design verification shall be completed prior to relying upon SSCs, or computer programs to perform its safety function and before installation becomes irreversible.

3.6.4 Where the design has been subjected to a verification in accordance with this policy, the verification process need not be duplicated for identical designs. However:

3.6.4.A The applicability of standardized or previously proven designs, with respect to meeting pertinent design inputs, shall be verified for each application.

3.6.4.B Known problems affecting the standard or previously proven designs and their effects on other features shall be considered.

3.6.4.C The original design and associated verification documentation shall be adequately documented and referenced in records of subsequent application of the design.

3.6.5 Where changes to previously verified designs have been made, design verification shall be required for the changes, including evaluation of the effects of those changes on the overall design, and on any design analysis upon which the design is based, that are affected by the change to previously verified design.

3.6.6 Design verification shall be performed by any competent individual(s) or group(s) other than those who performed the original design, but who may be from the same organization.

3.6.7 Design verification may be performed by the originator's supervisor, provided the supervisor did not specify a singular design approach, or rule out certain design considerations, and did not establish the design inputs used or, provided the supervisor is the only individual competent to perform the verification.

3.6.7.A Note: Cursory supervisory reviews do not satisfy the intent of this policy.

3.6.8 The responsible design organization shall identify and document the particular design verification method(s) used.

3.6.9 The results of design verification shall be documented with the identification of the verifier clearly indicated.

## 3.7 Design Reviews

3.7.1 Design reviews shall be controlled per approved procedures and performed to ensure that:

3.7.1.A The design inputs were correctly selected and incorporated into the design.

3.7.1.B Assumptions necessary to perform the design activity are adequately described and reasonable.

3.7.1.C Where necessary, the assumptions are identified for subsequent re-verifications when the detailed design activities are completed.

3.7.1.D Appropriate design methods and computer programs, when applicable, were used.

3.7.1.E The design output is reasonable compared to design inputs.

3.7.1.F The necessary design inputs and verification requirements are specified in the design documents or in supporting procedures or instructions.

## 3.8 Alternate Calculations

3.8.1 Alternate calculations shall use alternate methods to verify the correctness of original calculations or analyses. The appropriateness of assumptions, input data used, and the computer program, software, or other calculation method used shall also be reviewed.

## 3.9 Qualification Tests

3.9.1 If design adequacy is to be verified by qualification tests, the tests shall be in accordance with Policy Q-11.1 - *Test Control*.

3.9.2 Qualification tests shall demonstrate the adequacy of performance under conditions that simulate the most adverse design conditions. Where the test is intended to verify only specific design features, the other features of the design shall be verified by other means.

3.9.3 Required tests shall be controlled under appropriate operating modes and environmental conditions using the tools and equipment necessary to conduct the test in a manner to fulfill test requirements and test criteria.

3.9.4 Test procedures shall include or reference the test configuration and test objectives. Test procedures shall also include provisions for assuring that prerequisites and suitable environmental conditions are met, adequate instrumentation is available and used, appropriate tests and equipment are used, and necessary monitoring is performed.

3.9.5 Test results shall be documented and evaluated to assure that they satisfy test requirements and conform with acceptance criteria. The evaluation shall be documented and include identification of the individual performing the evaluation.

3.9.6 When tests are being performed on models or mockups, scaling laws shall be established, reviewed, and approved.

3.9.7 The results of model test work shall be subject to error analysis, where applicable, before using the results in final design work.

3.9.8 If qualification testing indicates that a modification to an item is necessary to obtain acceptable performance, then the modification shall be documented and the item modified and retested or otherwise verified to ensure satisfactory performance.

## 3.10 Design Change Control

3.10.1 Design changes shall be controlled according to the following requirements:

3.10.1.A Changes to final designs, field changes, modifications to operating facilities, and nonconforming items dispositioned use as-is or repair, shall be justified and shall be subject to design control measures commensurate with those applied to the original design.

3.10.1.B These design control measures shall include provisions to evaluate the effect of the changes on the overall previously verified design and ensure that the design analyses for the item are still valid.

3.10.1.C Changes shall be approved by the same affected groups or organizations that approved the original design documents.

3.10.1.D If an organization that originally was responsible for approving a particular design document is no longer responsible, then a new responsible organization shall be designated.

3.10.1.E The design organization approving the design shall have demonstrated competence in the specific design area of interest, and have an adequate understanding of the requirements and intent of the original design.

3.10.1.F When a significant design change is necessary because of an incorrect design, the design process and verification procedure shall be reviewed and modified as necessary. These design deficiencies shall be documented in accordance with Policy Q-16.1 - *Corrective Action.* Additionally, if the incorrect design causes constructed or partially constructed SSCs to be nonconforming, the affected items shall be controlled in accordance with Policy Q-15.1 - *Control of Nonconforming Items*.

3.10.1.G Nonconformances to design requirements dispositioned use-as-is or repair shall be subject to design change control measures commensurate with those applied to the

original design. Required as-built records shall reflect the use as-is or repair condition.

3.10.1.H Field changes shall be incorporated into affected design documents when such incorporation is appropriate, and when a field change is approved other than by revision to the affected documents.

3.10.1.I Design changes that impact related implementing documents or training programs shall be communicated to organizations affected by the change.

3.10.1.J Temporary changes to plant configuration shall be approved and controlled by appropriate procedures.

### 3.11 Software Design Control

3.11.1 The software design process shall be documented, approved by the responsible design organization, and controlled.

3.11.2 The requirements of Policy Q-03.2 - *Software Quality*, shall apply to quality affecting computer software design.

## 4 Specific DOE/RW-0333P QARD Requirements for IHLW Application

In addition to the requirements found in section 3 of this Policy, the following requirements are applicable to High Level Waste activities and shall be implemented.

4.1 Interface control shall include the assignment of responsibility among participating design organizations and groups for the development, review, approval, release, distribution, and revision of documents involving design interfaces.

### 4.2 Design Verification

4.2.1 In addition to reviewing completed design analyses and design output in accordance with Policy Q-06.1 - *Document Control,* and the design verification requirements identified in subsection 3.6 above, the specific design control requirements in this section shall be applied.

4.2.2 The particular design verification method shall be identified and its use justified.

4.2.3 Design verification shall be performed by competent individuals or groups other than those who performed the original design, but may be from the same organization. If necessary, this verification may be performed by the originator's supervisor provided:

4.2.3.A The supervisor did not specify a singular design approach or rule out certain design considerations and did not establish the design inputs used in the design; or the

supervisor is the only individual in the organization competent to perform the verification.

4.2.3.B The verification is not hastily and superficially done.

4.2.3.C The determination to use the supervisor is documented and approved, in advance, with concurrence of the QA organization.

4.2.4 Changes in previously verified designs shall require re-verification. Such verification shall include the evaluation of the effects of those changes on the overall previously verified design and on any design analysis upon which the design is based.

### 4.3 High Level Waste Form Production

4.3.1 Line management shall establish measures for controlling technical modifications to the waste form production process. Technical modifications subject to control shall include:

4.3.1.A Waste form and canistered waste form.

4.3.1.B Process control plans and other implementing documents.

4.3.1.C Waste Acceptance Product Specifications, Waste Form Compliance Plans, and Waste Form Qualification Reports.

## 5 Records

5.1 Design documentation and records shall include not only final design documents, such as drawings and specifications and revisions to those documents, but also documentation which identifies the important steps in the design process, including sources of design inputs that support the final design.

## 6 Responsibility

### 6.1 Manager of Engineering

6.1.1 The Manager of Engineering is responsible for the following:

6.1.1.A Establishing engineering organization policies and procedures for controlling design, engineering, configuration management, and regulatory positions.

6.1.1.B Ensuring that engineering activities are executed in accordance with the requirements of this policy.

6.1.1.C Implementing appropriate corrective actions, up to and including stop work, when work is not in compliance with the applicable design control requirements.

6.1.1.D Assuring design input documents are developed.

6.1.1.E Evaluating design-related environmental and safety impacts.

6.1.1.F Reviewing design change documents, as required.

6.1.1.G Participating in peer/technical reviews, as required.

6.1.1.H Assuring design output documents are consistent with design inputs and authorization basis documents.

## 6.2 Operations Manager

6.2.1 After acceptance of a system by Commissioning, the Operations Manager is responsible for ensuring that processing plant modifications, technical modifications, and temporary plant changes are accomplished in accordance with the requirements for design change control.

## 6.3 Quality Assurance Manager

6.3.1 The QA Manager is responsible for establishing the QA program requirements for design control, and reviewing engineering procedures that implement the stated requirements.

# Policy Q-03.2 Software Quality

## 1 Purpose and Applicability

1.1 This policy establishes requirements for the acquisition, development, modification, control, and use of quality-affecting software. Acquired software that is integral to the operations, maintenance, or calibration of measuring and test equipment, and has not been developed or modified for the project is controlled by Policy Q-12.1 - *Control of Measuring and Test Equipment,* and is exempt from the requirements of this policy. This policy defines requirements and responsibilities for controlling the quality of computer software.

1.2 This policy applies to organizations involved in quality-affecting software formulation and control. Any applications, other than software routines and macros, developed using these types of commercially available software shall meet the requirements of this policy. This policy applies to organizations that develop, procure, modify, maintain, operate, use, or retire software that is directly used in the design, analysis, and operation of structures, systems, and components (SSCs).

1.3 Requirements for electronic management of data are addressed in Supplement I - *Control of the Electronic Management of Data*.

## 2 Implementation Strategy

2.1 Computer software used for the control or support of work processes is to be controlled. Access to the computer software will be controlled.

2.2 Software quality assurance procedures will provide measures to ensure that computer programs used to develop or verify designs or establish safety envelopes (design analyses, models, or algorithms) are adequate for intended use. These measures include previous use, validation, or simulation.

2.3 The Business Services Manager is responsible for developing and maintaining procedures that identify software control requirements concurred with by the quality assurance organization that implement the requirements of this policy.

## 3 Policy

### 3.1 General

3.1.1 Computer software used to produce or analyze data, which is used directly in the design, analysis, and operation of SSCs, shall comply with the requirements of this policy, which is in accordance with ASME NQA-2a-1990, *Quality Assurance Requirements for Nuclear Facility Applications*, Subpart 2.7, *Quality Assurance Requirements of Computer Software for Nuclear Facility Applications*. The application of specific requirements shall be prescribed in software QA plan(s) and/or in written policies and procedures.

3.1.2 Software development shall proceed in a traceable, planned, and orderly manner.

3.1.3 The number of software life cycle phases and relative emphasis placed on each phase of software development will depend on the nature and complexity of the software.

3.1.4 The software design process shall be documented, approved by the responsible design organization, and controlled.

3.1.5 Acquired software or software previously developed not using this policy must be either: acquired through a procurement activity with appropriate quality controls; or be controlled and qualified in accordance with subsection 3.13 of this policy. In either case, software planning in accordance with subsection 3.3 and a defined software life cycle methodology, excluding a design document and code development, shall be applied.

3.1.6 When software is retired or the support for a software product is terminated, the software shall not be used.

## 3.2 Software Verification and Validation

3.2.1 Software verification and validation activities shall:

3.2.1.A Ensure that the software adequately and correctly performs intended functions.

3.2.1.B Ensure that the software does not perform any unintended function that either by itself or in combination with other functions can degrade the entire system.

3.2.1.C Be planned and performed for each system configuration, which may impact the software.

3.2.2 Software verification shall be performed during the software development to ensure that the products of a given life cycle phase fulfill the requirements of the previous phase or phases.

3.2.3 The results of the verification and validation activities shall be documented with the identification of the verifier and responsibilities indicated.

3.2.4 Software verification methods shall include any one or a combination of design reviews, alternate calculations, and test results performed during computer program development.

3.2.5 The extent of verification and the methods chosen are a function of the following:

3.2.5.A The complexity of the software.

3.2.5.B The degree of standardization.

3.2.5.C Similarity with previously proved software.

3.2.5.D Importance to safety.

3.2.6 Software verification and validation shall be performed by competent individual(s) or group(s) other than those who developed and documented the original design, but who

may be from the same organization with higher management approval and documented justification.

## 3.3 Software Planning

3.3.1 A software QA plan shall be developed for each new software project at the start of the software life cycle, or for procured software when it enters the purchaser's organization.

3.3.1.A Note: The software QA plan may be prepared individually for each software project, may exist as a generic document to be applied to software prepared within or procured by an organization, or may be incorporated into the overall quality assurance program.

3.3.2 The software QA plan shall identify:

3.3.2.A A description of the overall nature and purpose of the software.

3.3.2.B The software products to which it applies.

3.3.2.C The organizations responsible for performing the work and achieving software quality and their tasks and responsibilities.

3.3.2.D The required documentation.

3.3.2.E The standards, conventions, techniques, or methodologies which shall guide the software development, as well as methods to assure compliance to the same.

3.3.2.F The required software reviews.

3.3.2.G The methods for error reporting and corrective action.

## 3.4 Requirements Phase

3.4.1 Software design requirements shall be identified and documented and their selection reviewed and approved.

3.4.2 Software requirement documentation shall outline the requirements that the proposed software must satisfy.

3.4.3 The software requirements shall identify the operating system, function, interfaces, performance requirements, installation considerations, design inputs, and any design constraints of the computer program.

3.4.4 The requirements shall address the following, as applicable:

3.4.4.A Functionality—the functions the software is to perform.

3.4.4.B Performance—the time-related issues of software operation (i.e., speed, recovery time, response time).

3.4.4.C Design constraints imposed on implementation phase activities—any elements that will restrict design options.

3.4.4.D Attributes—non-time-related issues of software operation such as portability, acceptance criteria, access control, maintainability.

3.4.4.E External interfaces—interactions with people, hardware, and other software.

3.4.5 These requirements shall define the response of the software to anticipate classes of input data, and shall provide the detail and information necessary to either design the software or make an acquisition decision.

3.4.6 Software requirements shall be traceable throughout the remaining stages of the software development cycle.

3.4.7 The review of software requirements shall be performed at the completion of the software requirements documentation. This review shall assure that the identified requirements are complete, verifiable, consistent, and technically feasible. The review shall also assure that the requirements will result in feasible and useable code.

## 3.5 Design Phase

3.5.1 The software design shall be documented and shall define the computational sequence necessary to meet the software requirements.

3.5.2 Software design and implementation documentation shall include:

3.5.2.A A description of the major components of the software design as they relate to the software requirements.

3.5.2.B A description of the allowable or prescribed ranges for inputs and outputs.

3.5.2.C As applicable, numerical methods, mathematical models, control flow, physical models, control logic, data flow, process flow, data structures, process structures, and applicable relationships between data structures and process structures. This documentation may be combined with the documentation of the software design requirements or the computer program listings resulting from implementation of the software design.

3.5.3 Design phase software verification and validation activities shall consist of the following:

3.5.3.A Generation of test plans based on the requirements and design.

3.5.3.B Generation of design-based test cases.

3.5.3.C Review of the software design to ensure that the requirements are addressed.

3.5.4 A software design review shall be held at the completion of the software design documentation. The review shall meet the requirements of Policy Q-03.1 – *Design*

*Control* - subsection 3.7 – *Design Reviews*. This review shall evaluate the technical adequacy of the design approach, and assure internal completeness, consistency, clarity, and correctness of software design, and shall be traceable to the requirements.

## 3.6 Implementation Phase

3.6.1 The software design shall be translated into computer program(s) and the implemented software shall be analyzed to identify and correct errors.

3.6.2 Implementation phase software verification activities shall consist of the examination of source code listings to assure adherence to coding standards and conventions.

## 3.7 Testing Phase

3.7.1 Test requirements and acceptance criteria shall be provided or approved by the organization responsible for the design or use of the program to be tested unless otherwise designated. Required tests including (as appropriate) verification tests, hardware integration tests, and in-use tests shall be controlled. Test requirements and acceptance criteria shall be based upon applicable design or other pertinent technical documents.

3.7.2 Computer program test procedures shall provide for demonstrating the adherence of the computer program to documented requirements. Test procedures or plans shall specify the following as applicable:

3.7.2.A Required tests and test sequence.

3.7.2.B Required ranges of input parameters.

3.7.2.C Identification of the stages at which testing is required.

3.7.2.D Criteria for establishing test cases.

3.7.2.E Requirements for testing logic branches.

3.7.2.F Requirements for hardware integration.

3.7.2.G Anticipated output values.

3.7.2.H Acceptance criteria.

3.7.2.I Reports, records, standard formatting, and convention.

3.7.3 Test results shall be documented. Verification test results shall be evaluated by a responsible authority to assure that test requirements have been satisfied.

3.7.4 For those computer programs used for operational control, computer program test procedures shall provide for demonstrating required performance over the range of operation of the controlled function or process.

3.7.5 The computer test procedures shall also provide for evaluating technical adequacy through comparison of test results from alternative methods such as hand calculations, calculations using comparable proven programs, or empirical data and information from technical literature.

3.7.6 Software verification and validation documentation shall describe the tasks and criteria for accomplishing the verification of the software in each phase and the validation of software at the end of the development cycle. The documentation shall:

3.7.6.A Specify the hardware and software configurations pertinent to the software validation.

3.7.6.B Be organized in a manner that allows traceability to both software requirements and design.

3.7.6.C Contain the results of the execution of the verification and validation activities.

3.7.6.D Include the results of reviews and tests along with a summary of the status of the software (e.g., indication of incomplete design performance and application requirements).

3.7.7 Failure to successfully execute the test cases shall be reviewed to determine if modifications of the requirements, the design, the implementation, or the test plans and test cases are required.

3.7.8 Software validation of modifications to released software shall be subjected to regression testing to detect errors introduced during the modification of the software to verify that the modifications have not caused unintended adverse affects, or to verify that a modified software still meets specified requirements.

3.7.9 Upon completion of the testing phase, the development cycle documentation shall be reviewed and approved to assure completion and acceptability.

3.7.10 Depending on the complexity of the computer program being tested, testing may range from a single test and a series of tests performed at various stages of computer program development to verify correct translation between stages and proper working of individual modules, followed by an overall computer program test.

3.7.11 Regardless of the number of stages of testing performed, verification testing shall be sufficient to establish that test requirements are satisfied and that the computer program produces a valid result for its intended function.

## 3.8 Operations and Maintenance Phase

3.8.1 Upon acceptable validation of the software, in accordance with subsection 3.7 of this policy, the software shall be baselined and placed under configuration management controls in accordance with subsection 3.10 of this policy.

3.8.2 Further activity shall consist of maintenance of the software to remove latent errors (corrective maintenance), to respond to new or revised requirements (perfective maintenance), or to adapt the software to changes in the operating environment (adaptive maintenance).

3.8.3 Software modifications shall be approved, documented, verified and validated, and controlled.

3.8.4 In-use test procedures shall be developed and documented to permit confirmation of acceptable performance of the computer program in the operating system.

3.8.5 In-use test procedures shall be performed after the computer program is installed on a different computer, or when there are significant changes in the operating system.

3.8.6 Require periodic in-use manual or automatic self-check tests shall be prescribed and performed for those computer programs where computer program errors, data errors, computer hardware failures, or instrument drift can affect required performance.

3.8.7 In-use tests shall identify:

3.8.7.A Computer program tested.

3.8.7.B Computer hardware used.

3.8.7.C Test equipment and calibration, if applicable.

3.8.7.D Date of the test.

3.8.7.E Test or data records.

3.8.7.F Acceptability.

3.8.8 In-use tests shall be developed, performed and documented, and verified to provide confirmation of acceptance performance of software that is performing continuous data acquisitions of process control functions.

## 3.9 Installation and Checkout Phase

3.9.1 Software installation and checkout activities shall be performed and documented when the software is installed on a computer, or when there are changes in the operating system, to ensure that the software properly satisfies the requirements for its intended use.

3.9.2 Installation and checkout phase software verification and validation activities shall consist of:

3.9.2.A The execution of tests for installation and integration design.

3.9.2.B The documentation of the approval of the software for operational use.

## 3.10 Software Configuration Management

3.10.1 A configuration baseline shall be defined at the completion of each major phase of the software development and include appropriate control points within each major phase. Approved changes created subsequent to a baseline shall be added to the baseline. A baseline shall define the most recent approved software configuration.

3.10.2 A labeling system for configuration items shall be implemented includes:

3.10.2.A A definition of the baseline elements of each software baseline.

3.10.2.B Uniquely identifies each configuration item.

3.10.2.C Identifies changes to configuration items by revision.

3.10.2.D Provides the ability to uniquely identify each configuration of the revised software available for use.

3.10.3 Changes to software shall be formally controlled and documented.

3.10.3.A The software change documentation shall include:

3.10.3.A.1. A description of the change.

3.10.3.A.2. The rationale for the change.

3.10.3.A.3. The identification of the affected software baselines.

3.10.3.A.4. A release and control process for baseline elements.

3.10.3.B The changes shall be formally evaluated and approved by the organization responsible for the original design, unless an alternate organization has been given the authority to approve the changes.

3.10.3.C Only authorized changes shall be made to software baselines.

3.10.3.D Appropriate verification activities shall be performed for the change.

3.10.3.E The change shall be appropriately reflected in documentation and traceability of the change to the software design requirement shall be maintained.

3.10.3.F Appropriate acceptance testing shall be performed for the change.

3.10.4 The information that is needed to manage a configuration shall be documented and transmitted to all organizations affected by the change. This information shall identify the approved configuration, the status of proposed changes to the configuration, the status of approved changes, the history of the changes including descriptions, and information to support the functions of configuration identification, and configuration control.

## 3.11 Defect Reporting and Resolution

3.11.1 The defect reporting and resolution system shall be integrated with the software configuration management system.

3.11.2 Software defect reporting and resolution systems shall include the following controls:

3.11.2.A Problems are identified, evaluated, documented, and, if required, corrected.

3.11.2.B Problems are assessed for impact on past and present applications of the software by the responsible organization.

3.11.2.C Corrections and changes shall be controlled in accordance with applicable configuration change control requirements.

3.11.2.D Notification along with preventive actions and corrective actions are provided to the user organizations.

3.11.3 If a defect is identified in software that adversely impacts previous applications, then the condition adverse to quality shall be documented and controlled in accordance with Policy Q-16.1 - *Corrective Action*.

3.11.4 A software defect reporting and resolution system shall be implemented for software errors and failures to assure that problems are promptly reported to impacted organizations and to assure formal processing of problem resolutions.

## 3.12 Procurement

3.12.1 Individuals or organizations developing and supplying software shall be required to have policies and procedures that meet the applicable requirements of this policy as specified in procurement documents.

3.12.2 The documentation that is required by this policy shall be delivered or made available by the supplier to the purchaser.

3.12.3 The organization providing software services, such as verification and validation, shall have a plan(s) for software quality assurance that meets the requirements of this policy as specified in procurement documents. The user organization shall determine the adequacy of this plan.

3.12.4 Software errors and failures shall be reported between the supplier and purchaser in accordance with subsection 3.11 – *Defect Reporting and Resolution*.

3.12.5 Upon receipt of the software from the supplier, the purchaser assumes responsibility of the applicable requirements of this policy.

## 3.13 Software Developed Not Using This policy

3.13.1 Unqualified software in which the history of the software is not known, but the software is required to be used in quality activities shall meet the following requirements:

3.13.1.A Software that was previously developed not using this policy shall be placed under configuration controls prior to use.

3.13.1.B The user organization shall perform, document and provide for an independent review and evaluation to:

3.13.1.B.1. Determine its adequacy to support software operation and maintenance.

3.13.1.B.2. Identify the activities to be performed and documents required in order for the software to be placed under configuration management as a minimum, these activities include:

3.13.1.B.2.1. User application requirements.

3.13.1.B.2.2. Test plans and test cases required to validate the software for acceptability.

3.13.1.B.2.3. User documentation required in accordance with subsection 3.15 of this policy.

3.13.1.B.2.4. Upon independent review and approval of the above activities, the software shall be placed under configuration control in accordance with subsection 3.10 of this policy.

## 3.14 Access Control

3.14.1 To the extent appropriate, controls shall be established to permit authorized access and prevent unauthorized access to a computer system.

## 3.15 User Documentation

3.15.1 User documentation, as a minimum, shall include:

3.15.1.A User instructions that contain an introduction, a description of the user's interaction with the software, and a description of any required training necessary to use the software.

3.15.1.B Input and output specifications.

3.15.1.C Input and output formats.

3.15.1.D A description of systems limitations.

3.15.1.E A description of anticipated errors and how the user can respond.

3.15.1.F Information for obtaining user and maintenance support.

# 4 Specific DOE/RW-0333P QARD Requirements for IHLW Applications

In addition to the requirements found in section 3 of this Policy, the following requirements are applicable to High Level Waste activities and shall be implemented.

## 4.1 Implementation Phase

4.1.1 The design shall be translated into source code and resulting executables necessary to perform the functions required.

4.1.2 The source code and resulting executables shall adhere to the design specifications.

4.1.3 User information shall be developed, documented, and reviewed in accordance with the design to delineate how to use the software, including the following, as applicable:

4.1.3.A Instructions that contain an introduction, description of the user's interaction with the software, and a description of any required training necessary to use the software.

4.1.3.B Input and output specifications.

4.1.3.C Data files, input and output data, defaults, and file formats.

4.1.3.D A description of the allowable and tolerable ranges for inputs and outputs.

4.1.3.E Anticipated errors and how the user can respond.

4.1.3.F The hardware and software environments.

4.1.3.G Available sample problems.

4.1.3.H Installation procedures.

4.1.4 Software routines or macros that are documented in each product in which they are used and independently verified by visual inspection or hand calculation, without recourse to the original, shall have limited requirements applied as follows:

4.1.4.A Identification, including version of the software routine or macro.

4.1.4.B Documentation that includes inputs, computer program-generated correct results for a specified range of input parameters, computer program-generated evidence of the programmed algorithms or equations (e.g., computer program listings and spreadsheet cell contents), and verification results.

4.1.4.C Identification, including version of the commercially available software used to develop the routine and macro.

4.1.5 Software shall be placed under configuration management control as each baseline element is approved. Software shall not be used in quality-affecting activities unless it is obtained and limited to received copies from software configuration management.

### 4.2 Control of the Use of Software

4.2.1 Quality-affecting software shall be controlled and documented, and the use of released software items such that comparable results can be obtained, with any difficulties explained, through independent replication of the process.

4.2.2 Use of software shall be independently reviewed and approved to ensure that the software selected is suitable to the problem being solved.

4.2.3 If the use of software items falls outside the range of validation as baselined, changes shall be made to the appropriate baseline elements prior to use.

4.2.4 Documentation for the receipt of software obtained from software configuration management in accordance with this policy shall be provided and maintained for all software in operation or use.

## 5 Records

5.1 Record copies of required documentation shall be retained with other project records as required by codes, standards, specifications, plans, or procedures.

5.2 Records designated in implementing documents as quality assurance records shall be controlled in accordance with Policy Q-17.1 - *Quality Assurance Records.*

5.3 Verification test records shall identify:

5.3.1 Computer program tested.

5.3.2 Computer hardware used.

5.3.3 Test equipment and calibration, where applicable.

5.3.4 Date of test.

5.3.5 Tester or data recorder.

5.3.6 Simulation models used, if applicable.

5.3.7 Test problems.

5.3.8 Results and acceptability.

5.3.9 Action taken in connection with any deviations.

5.3.10 Person evaluating the test results.

# 6 Responsibilities

## 6.1 Functional Manager

6.1.1 The Functional Managers are responsible for:

6.1.1.A Establishing procedures to implement the software QA program.

## 6.2 Quality Assurance Manager

6.2.1 The QA Manager is responsible for:

6.2.1.A Identifying quality assurance requirements and policies.

6.2.1.B Assuring that QA procedures and processes are developed and maintained.

6.2.1.C Providing technical assistance/guidance to directors, managers, and staff in meeting QA requirements.

6.2.1.D Providing independent oversight of activities to ensure compliance with applicable regulations and requirements.

## 6.3 Project Director

6.3.1 The Project Director is responsible for:

6.3.1.A Ensuring that a software QA program and software configuration management is established, documented, and implemented in accordance with the requirements of this policy and applicable DOE orders.

6.3.1.B Designating individuals or organizations responsible for implementing this policy (e.g., technical support organization) and defining the interfaces with external organizations.

## 6.4 Business Services Manager

6.4.1 The Business Services Manager is responsible for:

6.4.1.A Development and maintenance of a program for the control of project software in accordance with all applicable laws, regulations, and requirements.

6.4.1.B Ensuring that the program implemented for control of software includes all phases of software life cycle, including, but not limited to, procurement, verification and validation, and use.

6.4.1.C Mediating and resolving software QA program issues that have not been resolved at subordinate levels.

## 6.5 Operations Manager

6.5.1 The Operations Manager is responsible for developing and implementing procedures for the control of process modeling software.

# Policy Q-04.1 Procurement Document Control

## 1 Purpose and Applicability

1.1 This policy identifies requirements and responsibilities to ensure that procurement documents, and changes thereto, contain appropriate technical and quality assurance requirements.

1.2 This policy applies to organizations and employees involved in the processing of documents for the procurement of quality affecting items and services.

## 2 Implementation Strategy

2.1 Technical, administrative, and quality requirements applicable to items or services being procured are to be identified and specified in procurement documents. These requirements include applicable codes, regulations and industry standards, tests and inspections, traceability, and special procedures or instructions. Procurement documents are to identify acceptance methods and criteria for acceptance or rejection of items or services.

2.2 Procedures will provide specific requirements and guidelines to initiate purchase requisitions, procurement specifications, and other procurement documents. These procedures will define appropriate controls for the selection, suitability determination, evaluation, and receipt of items or services being procured as well as controls that prevent the introduction of suspect or counterfeit items onto the project. These procedures are to ensure procured items and services meet established requirements and perform as specified. Procurement documents are to be developed utilizing approved procedures concurred with by the quality assurance organization that implement the requirements of this policy.

2.3 The procurement processes are part of the core function of Develop/Implement Controls of the Integrated Safety Management.

## 3 Policy

### 3.1 General

3.1.1 Applicable design bases and other requirements necessary to assure adequate quality shall be included or referenced in documents for procurement of items and services.

3.1.2 To the extent necessary, procurement documents shall require suppliers to have a documented QA program consistent with the applicable requirements of this policy.

3.1.3 When deemed appropriate, the purchaser shall permit some or all supplier work to be performed under the purchaser's or another affected organization's QA program provided the work is adequately addressed. In these cases, procurement documents shall specify that the purchaser's or another organization's implementing documents are applicable to the supplier, and that the purchaser shall provide these applicable documents to them.

3.1.4 Procurement processes and controls shall include provisions for preventing the procurement of suspect and counterfeit items.

**Policy Q-04.1 Procurement Document Control**

## 3.2 Procurement Document Contents

3.2.1 Procurement documents issued at all tiers of procurement shall include provisions for the following, as deemed necessary by the purchaser, and identify the revision level or change status on each document.

3.2.2 Procurement documents shall include a statement of the scope of work to be performed by the supplier.

3.2.3 Technical requirements shall be specified in the procurement documents. These requirements shall be specified, as appropriate, by reference to specific drawings, specifications, codes, standards, regulations, procedures, or instructions, including revisions thereto, that describe the items or services to be furnished.

3.2.4 The procurement documents shall identify appropriate test, inspection, and acceptance criteria for determining acceptability of the item or service.

3.2.5 QA program requirements shall be specified in procurement documents. These requirements shall be consistent with the importance and/or or complexity of the item or service being procured.

3.2.6 The procurement documents shall require the supplier to incorporate the appropriate QA requirements in subtier procurement documents.

3.2.7 QA requirements shall include provisions for establishing hold points beyond which work cannot proceed without purchaser authorization.

3.2.8 The procurement documents shall provide for access to the supplier's and subtier supplier's facilities and records for surveillance, inspection, or audit by the purchaser, its designated representative, or others authorized by the purchaser.

3.2.9 The procurement documents shall identify the documentation required to be submitted for information, review, or approval by the purchaser. The time of submittal shall also be established.

3.2.10 When the purchaser requires the supplier to maintain specific records, the retention times and disposition requirements shall be prescribed.

3.2.11 The procurement documents shall specify the purchaser's requirements for the supplier's reporting of nonconformances and the purchaser approval of the disposition of nonconformances.

3.2.12 The procurement documents shall specify the supplier's requirements to identify spare and replacement parts or assemblies, special tools required, and the related technical and quality assurance data required for ordering these parts, tools and assemblies.

3.2.13 Tests, inspections, and acceptance requirements that the purchaser will use to monitor and evaluate the performance of the supplier shall be specified.

### 3.3 Procurement Document Review and Approval

3.3.1 A review of the procurement documents, and changes thereto, shall be made and documented prior to award to assure that documents transmitted to prospective supplier(s) include all appropriate technical and QA provisions to assure that items or services will meet the specified requirements.

3.3.2 Technical or QA program changes made as a result of bid evaluations or negotiations shall be incorporated into the procurement documents.

3.3.3 Procurement document review shall be performed by personnel who have access to pertinent information and who have an adequate understanding of the requirements and intent of the procurement documents.

3.3.4 Procurement document reviewers for Quality Level items and activities shall include representatives from the technical and QA organizations.

3.3.5 Procurement document reviews shall be performed and documented in accordance with Policy Q-06.1 - *Document Control*, prior to issuance of the procurement documents to the supplier.

3.3.6 Procurement documents shall be approved by the originating organization.

### 3.4 Procurement Document Changes

3.4.1 Changes to the scope of work, technical requirements, QA program requirements, right of access, documentation requirements, nonconformances, hold points, and lists of spare and replacement parts delineated in procurement documents shall be subject to the same degree of control as used in the preparation of the original documents.

3.4.2 Evaluation of procurement document changes as a result of proposal/bid evaluation or negotiations and the resulting impact shall be completed before the contract is awarded.

3.4.3 This evaluation shall consider the following:

3.4.3.A The appropriate requirements as specified in this section.

3.4.3.B Additional or modified design criteria.

3.4.3.C Analysis of exceptions or changes requested or specified by the supplier and a determination of the impact such changes have on the intent of the procurement documents or quality of the item or service to be furnished.

## 4 Specific DOE/RW-0333P QARD Requirements for IHLW Applications

4.1 All applicable DOE/RW-0333P QARD requirements have been included in subsection 3 – *Policy.*

# 5 Records

5.1 No additional records requirements are applicable to this policy.

# 6 Responsibilities

## 6.1 Functional Organization

6.1.1 The designated Functional Organization is responsible for:

6.1.1.A Reviewing and approving the technical provisions of Quality Level (Q) purchase requisitions.

6.1.1.B Assuring that appropriate technical requirements and administrative controls for the specified items or services have been properly specified.

## 6.2 Requesting Organization

6.2.1 Organizations requesting procurement of Q items or services are responsible for documenting the requirements for the specified items or services by providing requisite ordering information, and ensuring adequacy of the documentation used to initiate a procurement and any subsequent changes. The manager of the requesting organization has the responsibility to verify that any requisitions and any attached documents have been properly reviewed and approved and meet the requirements specified in this policy for initiating procurement.

## 6.3 Acquisition Services Manager

6.3.1 The Acquisition Services Manager, reporting to the Deputy Project Manager, has the overall responsibility for developing and approving procedures and documents that control the procurement quality process. The Acquisition Services Manager is responsible for developing and implementing the procedures that provide a detailed methodology for reviewing and approving requisitions, amendments to requisitions, bid packages, and other procurement documents.

6.3.2 The Acquisition Services Manager is responsible for solicitation and receipt of proposals and ensuring that requirements specified in the procurement documents, including quality requirements, are accurately transcribed into the final purchase documents.

6.3.3 The Acquisition Services Manager is also responsible for formulating and administering subcontracts, ensuring that requirements specified in the subcontract documents, including quality requirements, are accurately transcribed into the subcontract documents.

6.3.4 The Acquisition Services Manager is also responsible for performing source inspections.

## 6.4 Manager of Engineering

6.4.1 The Manager of Engineering has the responsibility for developing and approving procedures and documents, including specifications that control the procurement quality requirements.

## 6.5 Quality Assurance Manager

6.5.1 The QA Manager is responsible for:

6.5.1.A Evaluating and qualifying of suppliers.

6.5.1.B Performing receipt inspection of designated quality-affecting items.

6.5.1.C Performing supplier audits.

6.5.1.D Reviewing and approving the quality provisions of Q requisitions.

6.5.1.E Assuring that appropriate quality requirements and administrative controls for the specified items or services have been properly specified in procurement requisitions.

## 6.6 Business Services Manager

6.6.1 The Business Services Manager has the responsibility for administering the Prime Contract and for developing and approving procedures and documents that control the Prime Contract.

# Policy Q-05.1 Instructions, Procedures, and Drawings

## 1 Purpose and Applicability

1.1 This policy identifies requirements and responsibilities to ensure that quality-affecting activities are prescribed by and performed in accordance with instructions, procedures, and drawings of the type appropriate to the circumstances. In addition, instructions, procedures and drawings shall include, as appropriate, reference to the necessary quantitative or qualitative acceptance criteria for determining that the prescribed results have been satisfactorily attained.

1.2 This policy applies to project organizations responsible for the development, review, approval, maintenance, use, and cancellation of new and revised instructions, procedures, and drawings for activities affecting quality. This policy is designed to ensure that personnel take responsibility for the quality of their own work and that they follow prescribed standards, procedures, instructions to accomplish work.

## 2 Implementation Strategy

2.1 The objective of the Integrated Safety Management System (ISMS) is to do work safely. To achieve that objective, work is to be performed to established technical standards and administrative controls, using approved instructions, procedures, or other appropriate mechanisms that are easily accessible to the worker. Work control procedures will be developed and implemented for management of work; to ensure compliance with applicable engineering, health, safety, environmental, construction, operational, and quality standards and technical requirements; and to enhance worker safety at all organizational levels.

2.2 Personnel performing work are responsible for the safety and quality of their work. This will be achieved by providing people with the necessary training and maintenance of their qualifications to assure competence commensurate with responsibilities of the job. This training will provide necessary knowledge of requirements for the work they perform and an understanding of the capability of the tools and processes they use. Working to established standards and controls will be consistent with expectations of the Integrated Safety Management core functions to develop/implement controls and perform work.

2.3 The project management system is designed to ensure that the following are clearly identified and conveyed to workers before beginning work based on the nature, hazards, or complexity:

2.3.1 Customer and data requirements for the work and final product (ISMS Core Function 1).

2.3.2 Acceptance criteria applicable to work and final product (ISMS Core Function 1).

2.3.3 Hazards associated with the work (ISMS Core Function 2).

2.3.4 Roles and responsibilities, authorities and interfaces (ISMS Principle 2).

2.3.5 Technical standards applicable to work and final product (ISMS Core Function 1 and 3).

2.3.6 Safety, administrative, technical, and environmental controls to be employed during the work (ISMS Core Function 3).

2.4 Management should ensure that those under their supervision have the skills (including knowledge and understanding of the capabilities of the processes being used), equipment, work process documents, and resources needed to accomplish their work.

2.5 Procedures, work instructions, or other means used to define work processes should be documented. The scope and detail of documentation should be commensurate with the complexity and importance of the work, the skills required to perform the work, and the hazards and risks or consequences of quality problems in the product, process, or service (ISMS Guiding Principle 6). Control of processes, skills, hazards, and equipment should be clearly specified, understood, and fully documented (ISMS Guiding Principle 5, Core Function 3). Procedures, instructions, and drawings must comply with the requirements of applicable technical standards, Safety Analysis Reports, codes, specifications, and other technical requirement documents. These procedures and instructions define the requirements for reviews by engineering, quality, operations, construction, health, safety and other affected organizations before approval. Personnel reviewing these procedures and instructions are to be assigned by their organization based on qualification, knowledge, experience, and competency in their area of responsibility.

2.6 Instructions, procedures and drawings are controlled in accordance with Policy Q-06.1 - *Document Control.*

2.7 Instructions, procedures and drawings are to be developed and concurred with by the quality assurance (QA) organization utilizing the requirements of this policy.

# 3 Policy

## 3.1 General

3.1.1 Activities affecting quality shall be prescribed by and performed in accordance with documented instructions, procedures, and drawings of the type appropriate to the circumstances that include or reference appropriate quantitative or qualitative acceptance criteria for determining that prescribed activities have been satisfactorily accomplished.

3.1.2 Activities affecting quality shall be described to a level of detail commensurate with the complexity of the activity and the need to assure consistent and acceptable results.

3.1.3 The need for and the level of detail in written procedures or instructions shall be determined based on the complexity of the task, the significance of the item or activity, work environment, and worker proficiency and capability (i.e., education, training, experience).

## 3.2 Types of Implementing Documents

3.2.1 Implementing documents include documents such as, instructions, procedures and drawings, with the exception of drawings governed by Policy Q-03-1-*Design Control.*

3.2.2 The type of document to be used to perform work shall be appropriate to the nature and circumstances of the work being performed.

## 3.3 Review and Approval of Implementing Documents

3.3.1 Implementing documents shall be reviewed, approved, and controlled in accordance with Policy Q-06.1 - *Document Control.*

## 3.4 Compliance with Implementing Documents

3.4.1 All individuals at the project shall comply with the implementing documents. However, when work cannot be accomplished as described in the implementing document, or accomplishment of such work would result in an unsafe condition or undesirable situation, the work shall not proceed. Work shall not be resumed until the implementing document is changed in accordance with the appropriate procedures to reflect safe and correct work practices.

## 3.5 Contents of Implementing Documents

3.5.1 Implementing documents shall include the following information as appropriate to the work to be performed:

3.5.1.A Responsibilities and organizational interfaces of the organizations affected by the document.

3.5.1.B Where work must be performed in a given sequence a description of the work to be performed including controls for altering the sequence of required inspections, tests, and other operations shall be established. The organization responsible for preparing the document shall determine the appropriate level of detail.

3.5.1.C Quantitative or qualitative acceptance criteria sufficient for determining that activities were satisfactorily accomplished, where necessary for work acceptance.

3.5.1.D Prerequisites, limits, precautions, process parameters, and environmental conditions, for testing and operational activities.

3.5.1.E Quality verification and hold points where appropriate.

3.5.1.F Methods for demonstrating that the work was performed as required (such as provisions for recording inspections and test results, checkoff lists, or signoff blocks).

3.5.1.G Identification of QA records generated by the implementing document.

3.5.1.H Identification of associated items and activities, where appropriate and applicable.

# 4 Specific DOE/RW-0333P QARD Requirements for IHLW Applications

4.1 All applicable DOE/RW-0333P QARD requirements have been included in subsection 3 – *Policy*.

# 5 Records

5.1 No additional record requirements are applicable to this policy.

# 6 Responsibilities

## 6.1 Managers

6.1.1 Managers are responsible for:

6.1.1.A Ensuring that activities within their area of responsibility are performed in accordance with documented instructions, procedures, and drawings.

6.1.1.B Ensuring that personnel are trained in the use of instructions, procedures, and drawings to achieve and maintain proficiency in their assigned tasks.

## 6.2 Quality Assurance Manager

6.2.1 The QA Manager is responsible for:

6.2.1.A Reviewing administrative and technical procedures, which implement requirements of the QA Manual.

6.2.1.B Reviewing procedures, which incorporate independent inspection.

## 6.3 Personnel

6.3.1 All personnel are responsible for:

6.3.1.A Following prescribed instructions, procedures, and drawings in the performance of their assigned tasks for activities that affect quality.

6.3.1.B Reporting errors or deficiencies in instructions, procedures, and drawings to their immediate management.

6.3.1.C Identifying conditions or activities for which instructions, procedures, and drawings are needed.

6.3.1.D Working to the most current document revision.

6.3.1.E Stopping work activities and informing their supervisors when it appears that adherence to a procedure is not possible or may result in an unsafe condition.

# Policy Q-06.1 Document Control

## 1 Purpose and Applicability

1.1 This policy identifies requirements and responsibilities to ensure that specified documents, either in hard copy or electronic media, including latest changes thereto, are controlled, reviewed for adequacy, approved for release, and distributed to and used at the location where the work is being performed.

1.2 This policy applies to organizations involved in development, review, approval, revision, distribution, or use of controlled documents.

## 2 Implementation Strategy

2.1 Documents are written, recorded, electronic media or pictorial information that describe, define, specify, report, or certify activities, requirements, procedures, results, or plant conditions. Documents are to be prepared, reviewed, approved, issued, used, and revised and maintained to prescribe processes, specify requirements, or establish design.

2.2 The Project Manager is responsible for developing and implementing the project procedure(s) that will require documents to be controlled, maintained, stored, protected, and capable of being retrieved in a timely manner. Record copies of documents are to be retained for their specified retention period. Documents will be prepared and, when specified, reviewed by cognizant individuals or organizations in accordance with a graded approach. Individuals or groups responsible for developing, reviewing, approving, issuing, and revising documents are to be identified in procedures. Guidance for the distribution and effective dates of new or revised documents will be established.

2.3 Revisions shall be reviewed and approved by those organizations or technical disciplines affected by the change. Alternative organizations may be designated to review and approve documents based on their technical competence and capability in the required functional areas. The revision process will provide for minor editorial changes and urgent changes to be processed expeditiously. Measures are to be provided to assure that approved changes are included in documents before implementation.

2.4 Controlled copies of approved documents are to be distributed manually or electronically and made available to the individuals responsible for performing the assigned tasks. Document control activities will include provisions for a master index and/or table of contents to identify the current revisions of controlled documents. Superseded/cancelled documents will be controlled to preclude their use and to ensure the use of correct revisions. Controls are to be established to ensure that the current revisions of approved procedures are identified and posted. Typical documents that will be controlled include project procedures, project instructions, special test procedures, and construction drawings.

2.5 The Project Manager is responsible for developing the document control procedures that are concurred with the quality assurance (QA) organization that contain the requirements of this policy.

# 3 Policy

## 3.1 General

3.1.1 The preparation, issue, and change of documents that specify technical requirements, quality requirements or prescribe activities affecting quality such as instructions, procedures, and drawings shall be controlled to ensure that correct documents are being employed.

3.1.2 Documents shall be maintained to show the configuration of the plant. This may include use of interim issue documents.

3.1.3 Documents defined in 3.1.1 above, including changes thereto, shall be reviewed for adequacy and approved for issue by authorized personnel.

3.1.4 The organizations and individuals responsible for the preparation, review, document approval, approval for release, distribution, and maintenance of controlled documents shall be assigned.

## 3.2 Distribution and Use of Documents

3.2.1 The distribution and use of documents, including changes and editorial corrections to documents, shall include the following controls:

3.2.1.A The documents to be controlled shall be identified.

3.2.1.B Controlled documents will be reviewed for completeness and approved prior to distribution.

3.2.1.C A method shall be established to ensure the correct controlled documents, either in hardcopy or electronic media, are distributed to, or made available to, and used at, the work location.

3.2.1.D Effective dates shall be established for approved implementing documents.

3.2.1.E A method shall be established to ensure the disposition of obsolete or superseded documents so they are controlled and not used to perform work.

3.2.1.F A method shall be established to identify the current status of each document that is required to be controlled.

## 3.3 Major Document Changes

3.3.1 Changes to documents, except minor changes, shall be reviewed and approved by those organizations or technical disciplines affected by the change.

3.3.2 The individuals reviewing document changes shall have access to pertinent document background data or information upon which to base their review and approval.

## 3.4 Minor Document Changes

3.4.1 Minor changes to documents, such as editorial corrections, shall not require that the revised documents receive the same review and approval as the original documents. The following are considered editorial changes:

3.4.1.A Correcting grammar or spelling.

3.4.1.B Re-numbering sections or attachments that do not affect the sequence of work.

3.4.1.C Changing the title or number of the document.

3.4.1.D Updating organizational titles.

3.4.1.D.1. Note: A change in an organizational title accompanied by a change in responsibilities is **not** considered an editorial correction.

3.4.2 The organizational position responsible for approving the document for release shall approve editorial corrections.

## 3.5 Incorporating Changes

3.5.1 Implementing documents shall define the method used to incorporate changes.

3.5.2 Implementing documents shall require that a history of changes to quality-affecting documents, including the reasons for the changes, be documented and maintained. This document history shall be reviewed each time additional changes to the document are proposed.

3.5.3 If the defined method for incorporating change is other than reissue of the entire controlled document, the implementing document shall define the maximum number of changes permitted prior to requiring reissue of the entire controlled document.

## 3.6 Expedited Document Changes

3.6.1 If an activity cannot be performed as listed in a document, and the change process would cause unreasonable delays, then an expedited change may be made at the work location by responsible management.

3.6.2 After the expedited change has been authorized, the changes shall be processed through the normal change process. This processing shall occur in a timely manner consistent with the type and nature of the documents being changed.

3.6.3 Implementing documents shall describe the process to control expedited changes according to the following requirements:

3.6.3.A The level of management with the authority to make expedited changes shall be identified.

3.6.3.B The time limits for processing expedited changes through the normal change process shall be specified.

3.6.3.C An evaluation of the work shall be performed if the normal review process results in a change that is different from the expedited change.

### 3.7 Document Review

3.7.1 Implementing documents and other documents that specify technical or quality requirements, including changes, shall be reviewed to the following requirements:

3.7.1.A Pertinent background information or data shall be made available to the reviewers.

3.7.1.B The review shall be performed by those other than the preparer.

3.7.1.C Reviewers shall be technically competent for the subject area of the document.

3.7.1.D The scope of the review shall consider all aspects of the document.

3.7.1.D.1. Each organization or technical discipline affected by the document shall review the document including subsequent changes (per paragraph 3.3.1).

3.7.1.D.2. The QA organization shall review all documents which directly implement the QAM requirements, including changes.

3.7.1.E Mandatory comments resulting from the review shall be documented and resolved before approving the document.

## 4 Specific DOE/RW-0333P QARD Requirements for IHLW Applications

In addition to the requirements found in section 3 of this Policy, the following requirements are applicable to High Level Waste activities and shall be implemented.

### 4.1 Document Review

4.1.1 Implementing documents and other documents that specify technical or quality requirements shall be reviewed to the following requirements:

4.1.1.A Review criteria shall be established before performing the review. The criteria shall consider applicability, correctness, technical adequacy, completeness, accuracy, and compliance with established requirements.

4.1.1.B The QA organization shall review implementing documents and changes thereto that translate the QARD into work processes. The QA organization also shall review changes to other documents if they were required to review the previous version, unless the QA organization has concurred that its review is no longer required.

4.1.1.C Each organization or technical discipline affected by the document shall review the document according to the established review criteria. Changes to the document shall be reviewed by those organizations or technical disciplines affected by the change.

# 5 Records

5.1 No additional record requirements are applicable to this policy.

# 6 Responsibilities

## 6.1 Manager of Engineering

6.1.1 The Manager of Engineering is responsible for establishing and implementing the document control program.

## 6.2 Project Administrative Services Manager

6.2.1 The Project Administrative Services Manager is responsible for developing and maintaining a records management system and for managing documents in accordance with the requirements of this policy.

## 6.3 All Personnel

6.3.1 Personnel who prepare, process, or use-controlled documents for activities affecting quality are responsible for complying with the requirements of this policy as defined in the implementing documents.

# Policy Q-07.1 Control of Purchased Items and Services

## 1 Purpose and Applicability

1.1 This policy identifies requirements and responsibilities for planning and executing procurement of items and services to assure conformance with specified requirements.

1.2 This policy applies to organizations responsible for planning and executing procurements to ensure that Quality Level (Q) purchased items and services meet specified requirements.

## 2 Implementation Strategy

2.1 Procurement procedures provide a detailed methodology for preparing, reviewing and approving purchase requisitions, amendments to requisitions, procurement specifications, bid packages, and other procurement documents. These procedures ensure procured items and services meet established requirements and perform as specified.

2.2 Engineering procedures will include a process for procurement of off-the-shelf commercial grade items and dedicating these items for safety-related applications. Engineering will initiate dedication by defining the critical characteristics of the item and associated verification requirements. These items will be subjected to specific inspections (Policy Q-10.1 - *Inspection*), tests (Policy Q-11.1 - *Test Control*), and/or evaluations to ensure that these items will perform properly in the safety-related application.

2.3 The procurement process is part of the Integrated Safety Management System (ISMS) core function of Develop/Implement Controls.

2.4 Prospective suppliers will be identified early in the design and procurement process. The Acquisition Services Manager is responsible for evaluating prospective suppliers, with assistance from the Engineering and quality assurance (QA) organizations. Supplier selection and evaluation will apply to the procurement of items and services in a manner consistent with their importance and a graded approach.

2.5 Prospective suppliers will be evaluated and selected on the basis of specified criteria published in procurement procedures and the procurement package. Evaluations are conducted by qualified assessors and supported by technical specialists when warranted by the nature of the procurement action. Items or services are to be procured from suppliers whose qualification results satisfy the requirements of the project quality assurance program. Those suppliers will be listed on an Approved Suppliers List (ASL) maintained by the QA organization.

2.6 Reviews of the suppliers' documentation and in-house assessment of the suppliers' capabilities are typically used for supplier selection based on the nature and application of items or services being procured. In addition, requalification and supplemental audits are performed on selected suppliers to verify compliance with the procurement requirements as indicated in Policy Q-18.1 - *Independent Assessment/Audit*.

**Policy Q-07.1 Control of Purchased Items and Services**

2.7 The quality of purchased items and services is verified at intervals during various phases of the procurement process. Frequency or necessity of verification are determined by requirements of the procurement documents, applicable specification, codes and standards, uniqueness, complexity, application of the item, quantity and frequency of the procurement, and previous quality-related performance of the supplier. Processes are established for monitoring suppliers to ensure compliance with QA and technical requirements.

2.8 Purchased items or services are accepted using approved procedures and method(s) specified by the requisitioning organization. Items are accepted by one or more of the following methods: source verification, receiving inspection, or post-delivery testing. In addition, a certificate of conformance with the appropriate receipt inspection may be used for acceptance of certain standard items. The certificate of conformance and inspection documentation is to be traceable to the item and identify the specific requirements met by the purchased item.

2.9 Procured services may be accepted by the review and technical verification of data/reports produced, performance, or by surveillance/audit of the activity. Performance of source verification and receiving inspection activities utilize procurement documents reviewed by the QA organization. Purchased items are examined for potential suspect/counterfeit part characteristics. If identified as a potential suspect/counterfeit part, they are evaluated and, as appropriate, dispositioned as nonconforming items.

2.10 Processes to ensure that approved suppliers continue to provide acceptable items and services are to be established and implemented. Source verification should be conducted at supplier facilities by qualified personnel to assure supplier, and subtier supplier compliance with procurement document requirements. These source verifications will consist of inspections and tests, including witness and hold points, and document verification as specified in procurement documents. Source verifications of subtier suppliers will also be performed as applicable.

2.11 Procured items are put into service only when the acceptance requirements (Policy Q-10.1 - *Inspection*) of the procurement documents have been satisfied. Nonconforming items and deficiencies will be recorded on a nonconformance (Policy Q-15.1 - *Control of Nonconforming Items*) or a deficiency report (Policy Q-16.1- *Corrective Action*) respectively. Identified deficiencies will be dispositioned and corrective action taken and verified prior to the use of the item. Information from nonconformance and deficiency reports is reviewed as part of the trend analysis process to identify supplier performance trends and problems (Policy Q- 16.1 - *Corrective Action*). Adverse trends and problems are reported to the Acquisition Services Manager and other responsible organizations.

2.12 Post-installation, functional, or pre-operational testing is to be performed after installation of procured items when specified (Policy Q-11.1 - *Test Control*). These tests will verify actual performance of the item against established criteria for the item and the system. Tests and in-service inspections will monitor the performance of the procured item against established criteria.

2.13 The Acquisition Services Manager is responsible for developing procedures for the procurement of items and services concurred with by the quality assurance organization that implement the requirements of this policy.

# 3 Policy

## 3.1 General

3.1.1 The procurement of items and services shall be controlled to assure conformance with specified requirements. Such control shall provide for the following as appropriate: source evaluation and selection, evaluation of objective evidence of quality furnished by the supplier, source inspection, audit, and examination of items or services upon delivery or completion.

## 3.2 Procurement Planning

3.2.1 Procurement planning shall:

3.2.1.A Identify procurement methods and organizational responsibilities.

3.2.1.B Identify what is to be accomplished, who is to accomplish it, how it is to be accomplished, and when it is to be accomplished.

3.2.1.C Identify and document the sequence of actions and milestones needed to effectively complete the procurement.

3.2.1.D Provide for the integration of the following activities:

3.2.1.D.1. Procurement document preparation, review, and change control according to the requirements of Policy Q-04.1 - *Procurement Document Control.*

3.2.1.D.2. Selection of procurement sources.

3.2.1.D.3. Proposal/bid evaluation and award.

3.2.1.D.4. Evaluation of supplier performance.

3.2.1.D.5. Verifications including any hold and witness point notifications.

3.2.1.D.6. Control of non-conformances.

3.2.1.D.7. Corrective action.

3.2.1.D.8. Acceptance of the item or service.

3.2.1.D.9. Identification of QA records per Policy Q-06.1 – *Document Control.*

3.2.1.E Be accomplished as early as possible and no later than at the start of those procurement activities that are required to be controlled.

3.2.1.F Be performed relative to the level of importance, complexity, and quantity of the item or service being procured and the supplier's quality performance.

3.2.1.G Include the involvement of the QA organization.

## 3.3 Source Evaluation and Selection

3.3.1 Prior to awarding a contract, the purchaser shall evaluate the supplier's capability to provide items or services in accordance with the requirements of the procurement documents. Supplier evaluation and selection and the results shall be documented and shall include one or more of the criteria listed below:

3.3.1.A Supplier's history of providing an identical or similar product which performs satisfactorily in actual use. The supplier's history shall reflect current capability.

3.3.1.B Supplier's current quality records supported by documented qualitative and quantitative information that can be objectively evaluated.

3.3.1.C Supplier's technical and quality capability as determined by a direct evaluation of the facilities, personnel, and implementation of the supplier's QA program.

3.3.2 Source verification shall be performed by personnel qualified in accordance with Policy Q-02.2 - *Personnel Training and Qualification*.

3.3.3 Subcontractors or suppliers qualified by Bechtel National Inc. (BNI) or the Washington Group International (WGI) may be selected without further evaluation as delineated above, provided the subcontractors or suppliers are qualified for the intended services. Before initiation of work, supplier's QA programs will be evaluated against project quality assurance requirements.

3.3.4 The organizational responsibilities for source evaluation and selection shall be identified, including provisions for input from the QA organization.

3.3.5 When sources are qualified by other Department of Energy (DOE) contractors, the qualification documentation shall be obtained and retained in files. As a minimum, they will be evaluated against project quality assurance requirements.

## 3.4 Proposal Bid Evaluation

3.4.1 The proposal/bid evaluation process shall include a determination of both the extent of conformance to the procurement document requirements, and the supplier's capability to conform to the technical and QA requirements.

3.4.2 The proposal/bid evaluation shall be performed by designated, technically qualified organizations including the QA organization.

3.4.3 The proposal/bid evaluation shall include the following subjects consistent with the importance, complexity, and quantity of items or services being procured:

3.4.3.A Technical considerations.

3.4.3.B QA program requirements.

3.4.3.C Supplier personnel.

3.4.3.D Supplier production capability.

3.4.3.E Supplier past performance.

3.4.3.F Alternatives.

3.4.3.G Exceptions.

3.4.4 Prior to award of the contract, the purchaser shall resolve or obtain commitments to resolve unacceptable technical and QA conditions resulting from the bid evaluation.

3.4.5 Supplier QA programs shall be evaluated before contract placement, and any deficiencies that would affect quality shall be corrected before starting work subject to this QA manual.

3.4.6 Supplier QA programs shall be accepted by the purchaser before the supplier starts work.

## 3.5 Control of Supplier Generated Documents

3.5.1 Controls shall be implemented to assure that the submittal, evaluation, acceptance, and control of supplier-generated documents are accomplished in accordance with the procurement document requirements. These controls shall provide for the acquisition, processing, and recorded evaluation of the QA, technical, inspection, and test documentation or data against established criteria.

## 3.6 Control of Changes in Items or Services

3.6.1 The purchaser and supplier shall assure that measures to control changes in procurement documents are established, implemented, and documented, and are in accordance with applicable quality assurance requirements.

## 3.7 Supplier Performance Evaluation

3.7.1 The purchaser of items and services shall establish measures to interface with the supplier and to verify supplier's performance. The measures shall include:

3.7.1.A Establishing an understanding between the purchaser and supplier of the requirements and specifications identified in the procurement documents.

3.7.1.B Requiring the supplier to identify planning techniques and processes to be used in fulfilling procurement document requirements.

3.7.1.C Reviewing supplier documents that are prepared or processed during work performed to fulfill procurement document requirements.

3.7.1.D Identifying and processing necessary change information.

3.7.1.E Establishing the method to be used to document information exchanges between purchaser and supplier.

3.7.1.F Establishing the extent of source verifications.

3.7.1.G Performing source verifications of subtier suppliers as applicable.

3.7.2 The extent of verifications shall be a function of the relative importance, complexity, and quantity of items or services being procured, and the supplier's quality performance.

3.7.3 Verifications shall be conducted as early as practical and shall not relieve the supplier of the responsibility for the verification of quality achievement.

3.7.4 Verifications shall include supplier audits used as a method of evaluating the supplier's performance, and evaluation of purchaser's documentation to aid in the determination of the effectiveness of the supplier's QA program.

## 3.8 Acceptance of Items or Services

3.8.1 Prior to offering the item or service for acceptance, the supplier shall assure that the item or service being furnished complies with the procurement requirements.

3.8.2 The supplier shall provide the purchaser with objective evidence that items or services conform to procurement documents. The documentation shall be available at the purchaser's facility before the item is installed or before the service is accepted.

3.8.3 Methods for accepting supplier furnished items or services shall include one or more of the following, as appropriate to the items or services being procured:

3.8.3.A Evaluating the supplier Certificate of Conformance.

3.8.3.B Performing one or a combination of source verification, receiving inspection, or post-installation test.

3.8.3.C Technical verification of the item or service.

3.8.3.D Surveillance or audit of the work.

3.8.3.E Review of objective evidence (i.e., certifications, stress reports, or personnel qualifications) for conformance to the procurement requirements.

## 3.9 Certificate of Conformance

3.9.1 When a Certificate of Conformance is used to accept an item or service the following requirements must be met:

3.9.2 The certificate shall identify the purchased material or equipment, such as by the purchase order number.

3.9.3 The certificate shall identify the specific procurement requirements met by the purchased material, equipment, or service, (i.e., codes, standards, and other specifications).

3.9.3.A Note: This may be accomplished by either including a list of the specific requirements, or by providing, on-site, a copy of the purchase order and the procurement specifications or drawings, along with a suitable certificate.

3.9.4 The procurement requirements identified shall include any approved changes, waivers, or deviations applicable to the subject material, equipment, or service.

3.9.5 The certificate shall identify any procurement requirements that have not been met, along with an explanation and the means for resolving the nonconformance.

3.9.6 The certificate shall be signed or otherwise authenticated by a person who is responsible for this QA function and whose function and position are described in the purchaser's or supplier's QA program.

3.9.7 The certification system, including the procedures to be followed in filling out a certificate and the administrative procedures for review and approval of the certificates, shall be described in the purchaser or supplier's QA program.

3.9.8 Means shall be provided to verify the validity of supplier certificates and the effectiveness of the certification system, such as during the performance of audits of the supplier or independent inspection or test of items. Such verification shall be conducted by the purchaser at intervals commensurate with the supplier's past quality performance.

## 3.10 Source Verification

3.10.1 When source verification is used, it shall be performed at intervals consistent with:

3.10.1.A The supplier's planned inspections, examinations, or tests at predetermined points.

3.10.1.B The importance and complexity of the item or service. Source inspection shall include monitoring, witnessing, or observed selected activities.

3.10.2 Source verification shall be implemented in accordance with plans to perform inspections, examinations, or tests at predetermined points.

3.10.3 Upon purchaser acceptance of source verification, documented evidence of acceptance shall be furnished to the receiving destination of the item, to the purchaser, and to the supplier.

## 3.11 Receiving Inspection

3.11.1 When receiving inspection is used to accept an item, purchased items shall be inspected as necessary to verify conformance to specified requirements, taking into account source verification and audit activities and the demonstrated quality performance of the supplier.

3.11.2 Purchased items shall be examined for potential suspect/counterfeit part characteristics. If identified as a potential suspect/counterfeit part, they shall be evaluated and, as appropriate, dispositioned as nonconforming items.

3.11.3 Receiving inspection shall verify by objective evidence such features as configuration; identification; dimensional, physical, and other characteristics; freedom from shipping damage; and cleanliness.

3.11.4 The inspection shall be planned and executed according to the requirements of Policy Q-10.1 - *Inspection*.

3.11.5 Receiving inspection shall be coordinated with a review for adequacy and completeness of supplier documentation when procurement documents require such documentation to be furnished prior to receiving inspection.

3.11.6 The inspection shall be performed in accordance with established inspection implementing documents.

## 3.12 Post-Installation Testing

3.12.1 When post-installation testing is used, post-installation test requirements and acceptance documentation shall be mutually established by the purchaser and supplier.

3.12.2 The test shall be in accordance with the requirements of Policy Q-11.1 - *Test Control*.

## 3.13 Acceptance of Services Only

3.13.1 In cases involving procurement of services only, such as third party inspection; engineering and consulting service; auditing; and installation, repair, overhaul, or maintenance work, the purchaser shall accept the service by any of the following methods:

3.13.1.A Technical verification of data produced.

3.13.1.B Surveillance or audit of the work.

3.13.1.C Review of objective evidence (i.e., certifications, stress reports, or personnel qualifications) for conformance to the procurement document requirements.

## 3.14 Control of Supplier Nonconformances

3.14.1 Methods for control and disposition of supplier nonconformances for items and services that do not meet procurement documentation requirements shall include the following:

3.14.1.A Evaluation of nonconforming items in accordance with Policy Q-15.1 - *Control of Nonconformances*.

3.14.1.B Submittal of nonconformance notice to the purchaser by supplier as directed by the purchaser. These submittals shall include supplier-recommended disposition (e.g., use as-is or repair) and technical justification.

3.14.1.C Nonconformances to the procurement requirements or purchaser approved documents which consist of one or more of the following, shall be submitted to the purchaser for approval of the recommended disposition:

3.14.1.C.1. Technical or material requirement is violated.

3.14.1.C.2. Requirement in supplier documents, which have been approved by the purchaser is violated.

3.14.1.C.3. Nonconformance cannot be corrected by continuation of the original manufacturing process or by rework.

3.14.1.C.4. The item does not conform to the original requirement even though the item can be restored to a condition such that the capability of the item to function is unimpaired.

3.14.1.D Purchaser disposition of the supplier's recommendation.

3.14.1.E Verification of the implementation of the disposition by the purchaser.

3.14.1.F Maintenance of records of supplier-submitted nonconformances.

## 3.15 Commercial Grade Items

3.15.1 Where the design uses commercial grade items, the purchaser can use the following requirements as an acceptable alternative to other requirements of this section for procuring and accepting items.

3.15.1.A The commercial grade item is identified in an approved design output document. An alternate commercial grade item may be applied, provided the cognizant design organization provides verification that the alternate commercial grade item will perform the intended function and will meet design requirements applicable to both the replaced item and its application.

3.15.1.B Source evaluation and selection, when deemed necessary by the purchaser based on complexity and importance to safety, shall be in accordance with subsection 3.3 - *Source Evaluation and Selection*, of this document.

3.15.1.C Prior to acceptance of a commercial grade item, the purchaser shall determine that:

3.15.1.C.1. The item did not sustain damage during shipment.

3.15.1.C.2. The item received was the item ordered, and the item satisfied the specified acceptance criteria.

3.15.1.C.3. Inspection or testing is accomplished to the extent determined by the purchaser, to ensure conformance with the purchaser's requirements.

3.15.1.C.4. Specified documentation, applicable to the item, was received and is acceptable.

# 4 Specific DOE/RW-0333P QARD Requirements for IHLW Applications

4.1 In addition to the requirements found in section 3 of this Policy, the following requirements are applicable to High Level Waste activities and shall be implemented.

## 4.2 Commercial Grade Items

4.2.1 Commercial grade items shall be identified in the purchase order by the manufacturer's published product description (e.g., catalog number).

4.2.2 Inspection or testing is accomplished, to the extent determined by the purchaser, to ensure conformance with the manufacturer's published requirements.

# 5 Records

5.1 No additional record requirements are applicable to this policy.

# 6 Responsibilities

## 6.1 Acquisition Services Manager

6.1.1 The Acquisition Services Manager is responsible for the following:

6.1.1.A Developing and maintaining implementing procedures for the procurement process.

6.1.1.B Implementing this process for procured items and services within the scope of this document from receipt of the requisition from the originator through the acceptance of the item or service by the purchaser.

6.1.1.C Formulating and administering subcontracts.

6.1.1.D Maintaining quality history records on suppliers who have demonstrated their ability to provide quality materials, equipment, or services or whose capability has been established by survey or audit.

6.1.1.E Establish and implement a source verification program to assure supplier, and subtier supplier, as applicable, compliance with procurement document requirements.

## 6.2 Manager of Construction

6.2.1 The Manager of Construction is responsible for the following:

6.2.1.A Carrying out requirements contained in this document through use of implementing documents. Specifically implementing this process for items and activities within the scope of this document at all facilities under construction.

6.2.1.B Disposition of supplier and contractor nonconformance when that responsibility has been assigned to Field Engineering by Design Engineering.

6.2.1.C Disposition of supplier and contractor nonconformance for field engineered designed items.

6.2.1.D Track supplier/subcontractor nonconformance, which require action at the site and assure that appropriate action is taken to resolve such nonconformance.

## 6.3 Manager of Engineering

6.3.1 The Manager of Engineering is responsible for the following:

6.3.1.A Reviewing of supplier and subcontractor engineering documents.

6.3.1.B Reviewing supplier reported design nonconformance.

6.3.1.C Supporting the supplier selection process.

6.3.1.D Developing procurement specifications.

6.3.1.E Reviewing bids for technical adequacy, as required.

## 6.4 Operations Manager

6.4.1 The Operations Manager is responsible for the following:

6.4.1.A Reviewing supplier and subcontractor operations-related documents.

6.4.1.B Reviewing supplier reported operations-related nonconformances.

6.4.1.C Supporting the supplier selection process.

6.4.1.D Developing operations-related procurement specifications.

## 6.5 Quality Assurance Manager

6.5.1 The QA Manager is responsible for the following:

6.5.1.A Concur with supplier QA Programs to the extent required in the procurement documents.

6.5.1.B Establish and implement a program of audits, to assure supplier compliance with procurement document requirements.

**Policy Q-07.1 Control of Purchased Items and Services**

6.5.1.C Review procurement documents to assure that quality requirements are correctly stated, inspectable, and controllable; that there are adequate acceptance/rejection criteria; that source surveillance or receipt inspection is specified; that minimum documentation to be supplied is specified; and that the procurement documents have been processed in accordance with established requirements.

6.5.1.D Establish and maintain an ASL which documents those suppliers qualified per specific project procurement requirements.

6.5.1.E Concurring in the selection of the source for procurements requiring submittal of a quality program, to assure that the source has been qualified in accordance with the requirements of this policy.

6.5.1.F Reviewing supplier quality verification documentation for items that have not been inspected at the source.

6.5.1.G Identify as nonconforming discrepant material received at the site for which a supplier's completed nonconformance report has not been received.

6.5.1.H Receiving inspection of designated quality-affecting items.

6.5.1.I Verification of field subcontractor's activities.

# Policy Q-08.1 Identification and Control of Items

## 1 Purpose and Applicability

1.1 This policy identifies requirements and responsibilities for identifying and controlling items to assure that only correct and accepted items are used or installed.

1.2 This policy applies to organizations involved in identifying and controlling items during research and development, design, procurement, construction, fabrication, commissioning, operation and maintenance phases of facilities for which Bechtel National, Inc. (BNI) has responsibility.

## 2 Implementation Strategy

2.1 Items will be maintained to prevent their damage, loss, or deterioration. Items include materials, equipment, components, appurtenances, assemblies, modules, parts, structures, subsystem units, subassemblies, and systems. Material identification and traceability requirements will be based on the specificity of the material identification requirements, its end use, and the consequences of failure.

2.2 Identification of items is to be maintained either on the item or in documentation traceable to the item. When required, items are to be identified from initial receipt or fabrication up to and including installation or use. Procedures will be established and used by workers to ensure that, when items having identification or traceability requirements are subdivided or sampled, identification will be transferred to each part, container of parts, or sample at the time of subdividing or sampling.

2.3 Controls will be established and implemented for workers to ensure that only correct and accepted items are used and installed. Where specified, items having limited shelf life, operating life or cycles are to be controlled to preclude use when such limits have been exceeded.

2.4 The requirements and responsibilities for handling, storing, and maintaining items are specified in Policy Q-13.1 - *Handling, Storage and Shipping*.

2.5 Project management is responsible for developing the necessary item identification and control procedures that are concurred with by the quality assurance organization that contain the requirements of this policy.

## 3 Policy

### 3.1 General

3.1.1 Controls shall be established to assure that only correct and accepted items are used or installed.

3.1.2 Temporary changes to plant conditions shall be approved and controlled by appropriate procedures.

**Policy Q-08.1 Identification and Control of Items**

## 3.2 Identification

3.2.1 Identification shall be maintained on the items or in documents traceable to the items, or in a manner, which assures that identification is established and maintained.

3.2.2 Items shall be identified from the initial receipt and fabrication of items up to and including installation or use. This identification shall relate an item to an applicable design or other pertinent specifying document.

## 3.3 Physical Identification

3.3.1 Physical identification shall be used to the maximum extent possible.

3.3.2 If physical markings are either impractical or insufficient, other appropriate means shall be employed (i.e., physical separation, labels, or tags attached to containers, or procedural control.)

3.3.3 When used, identification markings shall be applied using materials and methods, which provide a clear and legible identification and do not degrade the function or service life of the item.

3.3.4 When used, markings shall be transferred to each part of an identified item when subdivided and shall not be obliterated or hidden by surface treatment or coating unless other means of identification are substituted.

## 3.4 Traceability

3.4.1 When codes, standards, or specifications include specific identification or traceability requirements (i.e., identification or traceability of the item to applicable specification and grade of material; heat, batch, lot, part, or serial number; or specified inspection, test, or other records), the program shall provide such identification and traceability control.

## 3.5 Limited Life Items

3.5.1 Items having a limited calendar or operating life or cycles shall be identified and controlled to preclude use of items whose shelf life or operating life has expired.

## 3.6 Maintaining Identification of Stored Items

3.6.1 Provisions shall be made for the control of item identification consistent with the planned duration and conditions of storage, such as:

3.6.1.A Provisions for maintenance or replacement of markings and identification records due to damage during handling or aging.

3.6.1.B Protection of identifications on items subject to excessive deterioration due to environmental exposure.

3.6.1.C Provisions for updating existing plant records or related documentation.

# 4 Specific DOE/RW-0333P QARD Requirements for IHLW Applications

In addition to the requirements found in section 3 of this Policy, the following requirements are applicable to High Level Waste activities and shall be implemented.

4.1 Item identification methods shall ensure that traceability is established and maintained in a manner that allows an item to be traced to applicable design or other specifying documents.

4.2 Item traceability documentation shall ensure that the item can be traced at all times from its source through installation or end use.

4.3 If codes or standards do not include specific identification or traceability requirements, specifications shall specify identification and traceability methods appropriate to the item.

# 5 Records

5.1 No additional record requirements are applicable to this policy.

# 6 Responsibilities

## 6.1 Construction

6.1.1 Construction organizations that originate, use, store, and/or receive items are responsible for identifying and controlling the items in accordance with the requirements contained in this policy.

6.1.2 Warehouse personnel are responsible for acceptance of items in accordance with the requirements of this document.

## 6.2 Operations Manager

6.2.1 Operations organizations that originate, use, store, and/or receive items are responsible for identifying and controlling the items in accordance with the requirements contained in this policy.

6.2.2 After acceptance of a system by Commissioning, the Operations Manager is responsible for controlling temporary changes to plant conditions.

## 6.3 Acquisition Services Manager

6.3.1 Acquisition organizations that originate, use, store, and/or receive items are responsible for identifying and controlling the items in accordance with the requirements contained in this policy.

## 6.4 Quality Assurance Manager

6.4.1 The QA Manager is responsible for establishing and maintaining a system for identifying the quality status of items that encompasses, but is not limited to, acceptance, rejection, hold for inspection, and conditional use.

## 6.5 All Personnel

6.5.1 Each person performing project work is responsible for ensuring they only use and install the proper item and control the item appropriately as defined by project procedures.

# Policy Q-09.1 Control of Special Processes

## 1 Purpose and Applicability

1.1 This policy identifies requirements and responsibilities for controlling special processes, which affect the quality of items and services.

1.2 This policy applies to organizations performing special processes for product acceptance or continued service. These include processes such as welding, heat treating, brazing, chemical cleaning, soldering, bonding, and nondestructive examination.

## 2 Implementation Strategy

2.1 The objective of the Integrated Safety Management System (ISMS) is to do work safely. To achieve that objective, special process work is to be performed to established technical standards and administrative controls, using approved instructions, procedures, or other appropriate mechanisms. Procedures will be developed and implemented for control of special processes; to ensure compliance with applicable engineering, health, safety, environmental, security, and quality standards and technical requirements. Personnel performing the special process are responsible for the safety and quality of their work. This will be achieved by providing people with the necessary training and maintenance of their qualifications to assure competence commensurate with responsibilities of the job. This training will provide necessary knowledge of requirements for the work they perform and the capability of the tools and processes they use. Working to established standards and controls will be consistent with expectations of the Integrated Safety Management core functions of identifying hazards, developing controls, and working to prescribed processes.

2.2 Special process will be controlled through the use of approved procedures concurred with by the quality assurance organization that implement the requirements of this policy.

## 3 Policy

### 3.1 General

3.1.1 Special processes that control or verify quality, such as those used in welding, weld overlay, heat treating, chemical cleaning, and nondestructive examination, shall be performed by qualified personnel using approved procedures in accordance with specified requirements.

3.1.2 Special processes shall be controlled by instructions, procedures, drawings, checklists, travelers, or other appropriate means. These means shall assure that process parameters are controlled and that specified environmental conditions are maintained.

3.1.3 Special process instructions shall include or reference procedure, personnel, and equipment qualification requirements.

3.1.4 Individuals performing acceptance of special processes shall be independent of those performing the work being examined, and shall be appropriately qualified and certified.

3.1.5 Conditions necessary for accomplishment of the process shall likewise be included or referenced in special process instructions. These conditions shall include proper equipment, controlled parameters of the process, specified environment, and calibration requirements.

3.1.6 The requirements of applicable codes and standards, including acceptance criteria for the process, shall be specified or referenced in procedures or instructions.

3.1.7 For special processes not covered by existing codes and standards or where quality requirements specified exceed those of existing codes or standards, the necessary requirements for qualification of personnel, procedures, or equipment shall be specified or referenced in procedures or instructions.

3.1.8 The organization performing the special process shall adhere to the approved procedures or processes. Qualification of personnel, procedures, and equipment shall comply with specified requirements.

3.1.9 Nondestructive examination includes visual, radiography, magnetic particle, ultrasonic, liquid penetrant, eddy current, neutron radiography, and leak testing.

3.1.10 The affected organization shall establish implementing documents for the control and administration for the training, examination, and certification of nondestructive examination personnel that shall be in accordance with Policy Q-02.2 - *Personnel Training and Qualification.*

## 4 Specific DOE/RW-0333P QARD Requirements for IHLW Applications

In addition to the requirements found in section 3 of this Policy, the following requirements are applicable to High Level Waste activities and shall be implemented.

4.1 Processes to be controlled as special processes shall meet the following criteria:

4.1.1 The results are highly dependent upon the control of the process; or

4.1.2 The results are highly dependent upon the skill of the operator; and

4.1.3 The quality of the results cannot be readily determined by inspection or test of the item.

4.2 Based on the criteria in subsection 4.1 above, a list of the special processes that each affected organization will perform, or be responsible for performing, shall be established and maintained.

4.3 Special process implementing documents shall include or reference the conditions necessary for accomplishing the special process, including traceability between the item or product and individual performing the special process.

# 5 Records

5.1 Records shall be maintained for qualified personnel, processes, and equipment of each special process.

5.2 All records designated in implementing documents as quality assurance records shall be controlled in accordance with Policy Q-17.1 - *Quality Assurance Records*.

# 6 Responsibilities

## 6.1 Performing Organization

6.1.1 The organizations that perform special processes are responsible for ensuring that specific procedures or instructions for special processes are developed, reviewed, and approved by qualified personnel as required by applicable codes and standards.

6.1.2 The organizations that perform acceptance of special processes are responsible for ensuring that individuals performing acceptance of special processes are independent of those performing the work activity being examined, and are appropriately qualified and certified.

6.1.3 Personnel in Field Welding Engineering who accept UT or RT NDE results shall be independent of those individuals involved in the production of the work activities where the NDE is being performed.

## 6.2 Quality Assurance Manager

6.2.1 The QA Manager is responsible for reviewing special process procedures and work control documents that specify use of special processes to ensure the quality assurance requirements of this policy have been appropriately incorporated.

# Policy Q-10.1 Inspection

## 1 Purpose and Applicability

1.1 This policy identifies requirements and responsibilities for specifying, planning, performing, and reporting inspections used to verify the acceptance of items or activities. The inspection process is designed to prevent the inadvertent acceptance and use of nonconforming items.

1.2 This policy applies to organizations involved with the evaluation of conformance to specified requirements and acceptability of items and activities by inspection. Independent inspections performed by the Quality Control (QC) organization shall not relieve any organization performing work from their responsibility to provide items and services that meet quality requirements.

## 2 Implementation Strategy

2.1 Inspection of specified items, services, and processes is to be conducted using established acceptance and performance criteria. Examples of inspections include source, in-process, final, receipt, maintenance, and in-service. Administrative controls, including the use of status indicators, are to be used to preclude inadvertent bypassing of required inspections and inadvertent operation of nonconforming or indeterminate items or processes.

2.2 Inspections will be planned, controlled, and documented in accordance with established requirements (e.g., hold/witness points) and consistent with the results of the graded approach. Trained personnel will perform inspections using approved procedures. The engineering organization will establish level, extent, and acceptance criteria for inspections based on the critical characteristics of the item.

2.3 Inspection planning will ensure that inspection requirements are properly incorporated into inspection documents. Organizations performing inspections will be responsible for the planning of those inspections consistent with the owner/user needs. Inspection planning will include, as a minimum, item and process characteristics to be inspected; inspection techniques to be used; acceptance criteria; hold and witness points; and identification of the organization performing these inspections, as appropriate.

2.4 Inspection personnel will have the freedom to communicate inspection results to the appropriate level of management. Nonconforming items and processes being inspected will be controlled in accordance with the Policy Q-15.1 – *Control of Nonconforming Items*. After verification of corrective action implementation, the item or process will be re-inspected to the original or approved alternative acceptance criteria prior to being used or returned to service.

2.5 The Engineering and QA Managers are responsible for developing the necessary procedures that contain the requirements of this policy.

# 3 Policy

## 3.1 General

3.1.1 Inspections required to verify conformance of an item or activity to specified requirements or the continued acceptability of items in service shall be planned and executed.

3.1.2 Characteristics subject to inspection and inspection methods shall be specified. Inspection results shall be documented.

3.1.3 Inspection for acceptance shall be performed by qualified persons other than those who performed or directly supervised the work being inspected. These personnel shall not report directly to the immediate supervisor responsible for the item being examined.

3.1.3.A Note: Data recorders, equipment operators, or other inspection team members who are supervised by a qualified inspector are not required to be qualified inspectors.

3.1.4 When sampling procedures are used, they shall be based on valid statistical methods.

## 3.2 Inspection Requirements

3.2.1 Inspection requirements and acceptance criteria shall include specified requirements contained in the applicable design documents or other pertinent technical documents approved by the responsible design organization.

## 3.3 Inspection Hold Points

3.3.1 If mandatory QC independent inspection hold points are required beyond which work shall not proceed without specific consent of the designated representative, the specific hold points shall be indicated in appropriate documents.

3.3.2 Consent to waive specified hold points shall be recorded prior to continuation of work beyond the designated hold point.

## 3.4 Planning

3.4.1 Required in-service inspection or surveillance of structures, systems, or components (SSCs) shall be planned and executed by, or for, the organization responsible for operation.

3.4.2 Inspection planning shall be performed, documented, and include the following:

3.4.2.A Identification of each work operation where inspection is necessary to ensure quality and implementing documents that will be used to perform the inspections.

3.4.2.B Identification of characteristics to be inspected; methods of inspection; acceptance criteria; process monitoring methods to be employed; and when during the work process the inspections are to be made.

3.4.2.C Identification of the functional qualification level (i.e., Level I, II, or III Qualification Level) of personnel performing inspections.

3.4.2.D Identification of acceptance criteria.

3.4.2.E Identification of sampling requirements.

3.4.2.F Methods to record inspection results.

3.4.2.G Selection and identification of the measuring and test equipment to be used to perform the inspection to ensure that the equipment is calibrated and is of the proper type, range accuracy, and tolerance to accomplish the intended function.

3.4.2.H The final inspection shall be planned to arrive at a conclusion regarding conformance of the item to specified requirements.

3.4.2.I Hold and witness points, as appropriate.

3.5 In-Process Inspection and Monitoring

3.5.1 Inspection of items under construction or otherwise in process shall be performed as necessary to verify quality.

3.5.2 If inspection of processed items is impossible or disadvantageous, indirect control by monitoring of processing methods, equipment, and personnel shall be provided.

3.5.3 Both inspection and process monitoring shall be provided when control is inadequate without both.

3.5.4 A combination of inspection and process monitoring methods, when used, shall be performed in a systematic manner to ensure that the specified requirements for control of the process, and the quality of the item are met throughout the duration of the process.

3.5.5 Controls, where required, shall be established and documented for the coordination and sequencing of these activities at established inspection points during successive stages of the conducted process or construction.

## 3.6 Final Inspections

3.6.1 Completed items shall be inspected for completeness, markings, calibration, adjustments, protection from damage, or other characteristics as required to verify the quality and conformance to the specific requirements.

3.6.2 The acceptance of an item shall be documented and approved by qualified and authorized personnel.

**Policy Q-10.1 Inspection**

3.6.3 The inspection status of an item shall be identified according to Policy Q-14.1 - *Inspection, Test, and Operating Status*.

3.6.4 Final inspections shall include a record review of the results and resolution of nonconformances identified by prior inspections.

3.6.5 Any modifications, repairs, or replacements of items performed subsequent to final inspection shall require reinspection or retest, as appropriate, to verify acceptability.

3.6.6 Inspection documentation shall identify:

3.6.6.A The item inspected.

3.6.6.B The date of inspection.

3.6.6.C The name of the inspector, or the inspector's unique identifier, who documented, evaluated, and determined acceptability.

3.6.6.D The name of the data recorder, as applicable.

3.6.6.E The type of observation or method of inspection.

3.6.6.F The inspection criteria, sampling plan, or reference documents (including revision levels) used to determine acceptance.

3.6.6.G Results indicating acceptability of characteristics inspected.

3.6.6.H Reference to information on actions taken in connection with nonconformances.

3.6.6.I Measuring and test equipment used during the inspection, including the identification number and the most current calibrated date and/or the calibration due date.

3.6.7 Quality Records not previously examined prior to final inspection shall be examined for adequacy and completeness.

## 3.7 Qualifications of Inspection and Test Personnel

3.7.1 Personnel performing quality control independent inspections and tests to verify conformance of an item to specified acceptance criteria shall be qualified and certified according to the indoctrination, training, education, experience, and physical requirements of this policy and Policy Q-02.2 - *Personnel Training and Qualification*.

3.7.2 The initial capabilities of a candidate shall be determined by an evaluation of the candidate's education, experience, training, and either test results or capability demonstration. The evaluation shall be performed to the requirements of the applicable functional level, and education and experience requirements of this document.

## 3.8 Indoctrination and Training Qualification Requirements

3.8.1 Inspection and test personnel shall be indoctrinated to the technical objective and requirements of the applicable codes and standards, and the QA program requirements that are to be employed in executing their responsibilities.

3.8.2 Indoctrination and training shall be commensurate with scope; complexity; importance of the activities; special nature of the inspections or tests; and the education, experience, and proficiency of the person.

3.8.3 The need for a formal training program shall be determined. Training shall be provided as required to qualify personnel for performing inspections and tests.

3.8.4 On-the-job training, with emphasis on hands-on experience gained through actual performance of inspections and test, shall be included in the training program.

3.8.5 On-the-job training for personnel qualification shall be performed under the direct observation and supervision of a qualified person.

3.8.6 The documented verification of conformance shall be performed by the qualified person and not by the person being administered on-the-job training.

## 3.9 Functional Qualification Levels of Inspection and Test Personnel

3.9.1 Three levels of functional qualification (Levels I, II, and III) shall be used depending on the complexity of the functions involved. The criteria for each level are not limiting with regard to organizational position or professional status but, rather, are limiting with regard to functional work.

3.9.2 Level I Personnel Capabilities—Level I personnel shall be capable of performing and documenting the results of designated inspections or tests.

3.9.3 Level II Personnel Capabilities—Level II personnel shall have Level I capabilities for the corresponding category or class. Additionally, Level II personnel shall have demonstrated capabilities in:

3.9.3.A Inspection or test planning.

3.9.3.B Advanced preparation, including the preparation and setup of related equipment, as appropriate.

3.9.3.C Supervising or monitoring the inspections or tests.

3.9.3.D Supervising and certifying lower-level personnel.

3.9.3.E Evaluating the validity and acceptability of results.

3.9.4 Level III Personnel Capabilities—Level III personnel shall have Level II capabilities for the corresponding category or class. In addition, Level III personnel shall also be capable

of evaluating the adequacy of specific programs used to train, qualify, and certify the personnel.

## 3.10 Education and Experience Qualification Requirements

3.10.1 The requirements for education and experience shall be considered with recognition that other factors commensurate with the scope, complexity, or special nature of the inspections or tests affect the assurance that a person can competently perform a particular task. Other factors that demonstrate capability in a given job and the basis for their equivalency shall be documented.

3.10.2 Level I inspection personnel shall meet the following education and experience requirements:

3.10.2.A Two years of related experience in equivalent inspections or tests; or

3.10.2.B High school graduation or general equivalency diploma (GED) and six months of related experience in equivalent inspections or tests; or

3.10.2.C Completion of college level work leading to an associate degree in a related discipline plus three months of related experience in equivalent inspections or tests.

3.10.3 Level II inspection personnel shall meet the following education and experience requirements:

3.10.3.A One year of satisfactory performance as a Level I in the corresponding category or class; or

3.10.3.B High school graduation or GED plus three years of related experience in equivalent inspections or tests; or

3.10.3.C Completion of college-level work leading to an associate degree in a related discipline plus one year of related experience in equivalent inspections or tests; or

3.10.3.D Graduation from a four-year college plus six months of related experience in equivalent inspections or tests.

3.10.4 Level III inspection personnel shall meet the following education and experience requirements:

3.10.4.A Six years of satisfactory performance as a Level II in the corresponding category or class; or

3.10.4.B High school graduation plus ten years of related experience in equivalent inspections or tests; or high school graduation plus eight years of experience in equivalent inspections or tests with at least two years as a Level II and with at least two years associated with nuclear facilities; or, if not, at least sufficient training to be acquainted with the relevant quality assurance program aspects of a nuclear-related facility; or

3.10.4.C Completion of college-level work leading to an associate degree and seven years of related experience in equivalent inspections or tests with at least two years of this experience associated with nuclear facilities; or, if not, at least sufficient training to be acquainted with the relevant quality assurance program aspects of a nuclear-related facility; or

3.10.4.D Graduation from a four-year college plus five years of related experience in equivalent inspections or tests with at least two years of this experience associated with nuclear facilities; or, if not, at least sufficient training to be acquainted with the relevant quality assurance program aspects of a nuclear-related facility.

## 3.11 Maintaining Qualification Documentation for Inspection and Test Personnel

3.11.1 Records of qualification, including re-qualification for inspection and test personnel, shall be established and maintained by the employer.

3.11.1.A Note: Records of the implementation for indoctrination and training may take the form of attendance sheets, training logs, or personnel training records.

3.11.2 Inspection and test personnel qualification documentation shall contain the information required for the initial qualification and the maintenance of qualification.

3.11.3 Documentation for each person shall be maintained and updated according to the following requirements:

3.11.3.A Removal of a person from performing in an area of certification when the responsible organization determines that the capabilities of the individual are not in accordance with the qualification requirements specified for the job as described in this section. This shall be documented at the time of removal.

3.11.3.B Reinstatement of certifications for the qualified area when the required capability has been demonstrated as described in this section. This shall be documented at the time of reinstatement.

3.11.3.C Continued performance in each certified area or re-determination of required capability as described in this section for each certified area shall be updated annually.

3.11.3.D Re-evaluation of job performance by evidence of continued satisfactory performance or re-determination of capability as described in this section. This shall be updated every three years.

3.11.4 Integrity of examinations shall be maintained by the employer or certifying agency through appropriate confidentiality of files and, where applicable, proctoring of examination. Copies of the objective evidence regarding the type(s) and content of the examination(s) shall be maintained by the employer in accordance with the requirements of Policy Q-02.2 - *Personnel Training and Qualification*.

### 3.12 Physical Qualification Requirements

3.12.1 The responsible organization shall identify any special physical characteristics needed in the performance of each activity including the need for initial and subsequent visual acuity and other physical examinations.

### 3.13 Certification of Qualifications

3.13.1 The qualification of inspection and test personnel shall be certified in writing by the responsible organization and document the following information:

3.13.1.A Employer's name.

3.13.1.B Identification of the person being certified.

3.13.1.C Activities, qualified inspection and test categories or class the individual is certified to perform.

3.13.1.D Basis of qualification, such as:

3.13.1.D.1. Education, experience, indoctrination, and training.

3.13.1.D.2. Test results, where applicable.

3.13.1.D.3. Capability demonstration results.

3.13.1.D.4. Results of periodic evaluations.

3.13.1.E Results of visual acuity and other physical examinations, when required.

3.13.1.F Signature of the employer's designated representative who is responsible for such certification.

3.13.1.G Date of certification or recertification and certification expiration.

## 4 Specific DOE/RW-0333P QARD Requirements for IHLW Applications

4.1 All applicable DOE/RW-0333P QARD requirements have been included in subsection 3 – *Policy*.

## 5 Records

5.1 Records of personnel qualification shall be established and maintained in accordance with Policy Q-17.1 - *Quality Assurance Records*. These records will include the certification of qualifications.

## 6 Responsibilities

## 6.1 Manager of Engineering

6.1.1 The Manager of Engineering is responsible for the identification of and selective application of appropriate acceptance criteria in implementing documents and specifications.

## 6.2 Quality Assurance Manager

6.2.1 The QA Manager is responsible for:

6.2.1.A The preparation and/or review of quality-affecting documents that establish inspection requirements.

6.2.1.B Planning, performing, documenting and reporting inspection and tests.

6.2.1.C Qualification and training of inspection personnel, and ensuring that appropriate inspections and tests are scheduled and performed.

# Policy Q-11.1 Test Control

## 1 Purpose and Applicability

1.1 This policy identifies requirements and responsibilities for planning and executing tests that are used to verify conformance of an item to specified requirements, or to demonstrate satisfactory performance for service. The test control process is designed to prevent the use of failed or untested items.

1.2 This policy applies to organizations involved in performing tests such as prototype qualification tests, component tests, production tests, proof tests, construction tests, operational and pre-operational systems tests, factory and site acceptance tests, integrated water runs, cold commissioning, hot commissioning and in-use tests.

1.3 Computer program test requirements are identified in Policy Q-03.2 - *Software Control.* Activities required to collect data (such as for siting or design input) are performed in accordance with Supplement III – *Scientific Investigation.*

## 2 Implementation Strategy

2.1 Testing of specified items and processes will be conducted using established acceptance and performance criteria. Establishment and implementation of the test procedures will include the use of testing methods to demonstrate that items and processes perform as intended. These procedures are to be structured to clearly distinguish between tests that verify design requirements and tests that verify operation within safety limits and requirements. Test procedures will be implemented by trained personnel.

2.2 Item and process test requirements, including specified acceptance criteria, will be provided or approved by the organization responsible for design. Engineering has the primary responsibility for establishing and approving test requirements and associated acceptance criteria. Designated operations personnel will review the test packages for impact on and interface with operating systems, and confirm that proposed testing will provide adequate verification that the equipment being tested will perform its design functions.

2.3 Administrative controls and status indicators will be used to preclude inadvertent bypassing or non-completion of required tests or operation of untested items or processes as required by Policy Q-14.1- *Inspection, Test and Operating Status.*

2.4 When items and processes do not meet documented test acceptance criteria, test personnel have the freedom to communicate these deficiencies to management, and the deficiencies are to be documented and dispositioned as required by Policy 15.1- *Control of Nonconforming Items.*

2.5 Inspection and acceptance testing processes are to be part of the mechanisms that confirm readiness to perform safely in the project's integrated safety management system. The testing results will also serve the feedback and improvement process of Integrated Safety Management.

2.6 Test controls will include the development, approval, and use of test procedures. These procedures will include the requirements of this policy.

# 3 Policy

## 3.1 General

3.1.1 Tests required to collect data, to verify conformance of an item or computer program to specified requirements, and to demonstrate satisfactory performance for service shall be planned and executed.

3.1.2 Required tests, including, as appropriate, prototype qualification tests, production tests, proof tests prior to installation, construction tests, pre-operational tests, site acceptance tests, in-use tests and operational tests shall be controlled. Computer program tests such as software design verifications shall be controlled in accordance with Policy Q-03.2, *Software Quality*.

## 3.2 Test Requirements

3.2.1 Test requirements and acceptance criteria shall be provided or approved by the responsible design organization.

3.2.2 Test requirements and acceptance criteria shall be based upon specified requirements contained in applicable design documents or other pertinent technical documents that provide requirements.

3.2.3 If temporary changes to the approved configuration of a facility are required for testing purposes, approval by the design authority and the organization responsible for the facility is required prior to performing the test.

3.2.4 The tests performed shall obtain the necessary data with sufficient accuracy for evaluation and acceptance.

## 3.3 Test Planning

3.3.1 Required tests shall be performed and documented in accordance with approved written procedures, work packages, or data sheets.

3.3.2 Test procedure reviews shall be documented and comments dispositioned and resolved prior to final review and approval by the responsible organization(s). The organization responsible for performing the test shall be responsible for obtaining the approval of test procedures for a test activity.

3.3.3 The type and extent of test controls is based on the functional classification, and design, technical, or operational requirements assigned to the structure, system, or component.

## 3.4 Use of Other Testing Documents

3.4.1 As an alternative to subsection 3.3 above, appropriate sections of related documents such as American Society for Testing and Materials (ASTM) methods, supplier manuals, or

related documents containing acceptance criteria may be used instead of preparing special test -implementing documents. If used, they shall incorporate the information directly into the approved test-implementing document, or shall be incorporated by reference in the approved test-implementing document.

3.4.2 Implementing documents shall include adequate supplemental instructions as required to ensure the required quality of the testing work.

## 3.5 Implementing Documents

3.5.1 Tests shall be performed in accordance with implementing documents that address the following requirements as applicable:

3.5.1.A Provisions for determining when a test is required, describing how tests are performed, and ensuring that testing is conducted by trained and appropriately qualified personnel.

3.5.1.B Test procedures shall include or reference the test configuration and test objectives.

3.5.1.C Test procedures shall also include provisions for assuring that suitable environmental conditions are met, adequate instrumentation is available and used, appropriate tests and equipment are used, and necessary monitoring is performed.

3.5.1.D Prerequisites shall include the following, as applicable: calibrated instruments, appropriate equipment, trained personnel, condition of test equipment and the item to be tested, suitable environmental conditions, and provisions for data acquisition.

3.5.1.E Test parameters affected by potential sources of uncertainty and error shall be identified and controlled.

## 3.6 Test Results

3.6.1 Test results shall be documented and their conformance with test requirements and acceptance criteria shall be evaluated by a qualified individual within the responsible organization to ensure the test results have been satisfied, and who does not have direct responsibility for the work being performed.

3.6.2 The test status of an item shall be identified in accordance with Policy Q-14.1 - *Inspection, Test, and Operating Status*.

## 3.7 Test Documentation

3.7.1 Test records shall be established and maintained to indicate the ability of the item to satisfactorily perform its intended function or to meet its documented requirements.

3.7.2 Test documentation shall identify the:

3.7.2.A Item or work product tested.

3.7.2.B Date of the test.

3.7.2.C Name of the tester and data recorders.

3.7.2.D Type of observation and method of testing.

3.7.2.E Identification of test criteria or reference documents used to determine acceptance.

3.7.2.F Results and acceptability of the test.

3.7.2.G Actions taken in connection with any nonconformances noted.

3.7.2.H Name of the person evaluating the test results.

3.7.2.I Identification of the measuring and test equipment used during the test, including the identification number and the calibration due date.

### 3.8 Qualification of Test Personnel

3.8.1 Personnel who perform testing to verify conformance of an item to specified acceptance criteria shall be qualified in accordance with Policy Q-10.1 – *Inspection* and Policy Q-02.2 - *Personnel Training and Qualification*.

3.8.2 Test engineers who prepare and direct testing activities shall meet the qualification requirements in Policy Q-02.2 - *Personnel Training and Qualification*.

## 4 Specific DOE/RW-0333P QARD Requirements for IHLW Applications

In addition to the requirements found in section 3 of this Policy, the following requirements are applicable to High Level Waste activities and shall be implemented.

4.1 Test planning shall include:

4.1.1 Identification of the implementing documents to be developed to control and perform tests.

4.1.2 Identification of item to be tested and the test requirements and acceptance limits, including required levels of precision and accuracy.

4.1.3 Specification of characteristics to be tested, test methods to be employed, and instructions for performing the test.

4.1.4 Test prerequisites that address calibrated instrumentation, appropriate and adequate test equipment and instrumentation, trained personnel, condition of test equipment and the item to be tested, suitably controlled environmental conditions, and provisions for data acquisition.

4.1.5 Mandatory hold points.

4.1.6 Methods to record data and results.

4.1.7 Provisions for ensuring that prerequisites for the given test have been met.

4.1.8 Selection and identification of measuring and test equipment based on the type, range, accuracy, and tolerance needed to accomplish the required measurements for determining conformance to specified requirements.

4.1.9 Identification of the functional qualification level of personnel performing tests when required.

4.2 Test documentation will also include the identification of the measuring and test equipment used during the test, including the identification number and most recent calibrated date.

# 5 Records

5.1 No additional record requirements are applicable to this policy.

# 6 Responsibilities

## 6.1 Organizations Performing Tests

6.1.1 Organizations performing tests are responsible for:

6.1.1.A Preparing test procedures, procedure change requests, or equivalent test planning documentation.

6.1.1.B Preparing data collection and/or data sheets (as required).

6.1.1.C Preparing test procedures and approving changes to test procedures.

6.1.1.D Obtaining appropriate reviews and approvals of test plans and procedures.

6.1.1.E Evaluating and accepting the test results/data that are generated by the test.

6.1.1.F Providing final disposition of test results/data.

6.1.1.G Initiating a nonconformance or deficiency report if acceptance test results do not meet specified acceptance criteria.

## 6.2 Manager of Engineering

6.2.1 The Manager of Engineering is responsible for providing and approving test requirements and acceptance criteria.

## 6.3 Organization or Personnel Performing Independent Verification

6.3.1 The verifying organization or personnel performing independent verification is responsible to see that test data and results are collected in accordance with test procedures and accurately recorded.

## 6.4 Quality Assurance Manager

6.4.1 The QA Manager is responsible for reviewing test control procedures and work control documents that specify use of test controls to ensure that quality assurance requirements of this policy have been appropriately incorporated.

# Policy Q-12.1 Control of Measuring and Test Equipment

## 1 Purpose and Applicability

1.1 This policy identifies requirements and responsibilities for controlling measuring and test equipment (M&TE).

1.2 This policy applies to organizations that use or calibrate measuring and test equipment for determining acceptance of items and activities, process monitoring, data collection, or other activities affecting quality.

1.3 Calibration and control measures are not applicable for rulers, tape measures, levels, and other such coarse measurement devices that provide adequate accuracy as received from the manufacturer.

## 2 Implementation Strategy

2.1 Procedures describing the controls applicable to M&TE will be established and implemented for workers that use and calibrate M&TE. Equipment used for inspections and tests is to be calibrated and maintained. Traceability and accountability of this equipment is required.

2.2 M&TE procedures will define what equipment is considered M&TE. Calibration and traceability requirements for this equipment are also to be defined and based on its use. M&TE typically include instruments, tools, gauges, reference and transfer standards, and nondestructive examination equipment.

2.3 Calibration of M&TE is to be performed by trained individuals at specified intervals or just prior to and after use, as established by documented requirements. Calibration frequencies are to be based on required accuracy, intended use, frequency of use, stability characteristics, and other conditions affecting M&TE performance. M&TE will be labeled, tagged, or otherwise controlled to indicate calibration status. M&TE identification will provide traceability to calibration and test data.

2.4 Accuracy of M&TE calibration standards is to be established to ensure equipment being calibrated will be within required tolerances. Calibration standards will be traceable to national standards. If no national standards exist alternative standards will be identified.

2.5 M&TE found to be out-of-calibration or out-of-tolerance is to be tagged or segregated. Such M&TE will not be used until it has been either successfully re-calibrated or replaced. The M&TE control procedures will require formal documented review of the usage of such equipment dating back to its last known in-calibration date (reverse traceability). This review is to determine if such use resulted in the acceptability of items or processes being either invalid or indeterminate. The basis for acceptance of these nonconforming or indeterminate items and processes will be formally evaluated and documented.

2.6 During construction activities for the project, Construction maintains and controls M&TE used for testing, inspection, calibration of other instruments, process verification, or data

collection for purposes of determining compliance with requirements. During commissioning activities the Operations Department will maintain and control M&TE used for testing, inspection, calibration of other instruments, process verification, or data collection for purposes of determining compliance with requirements. Each respective organization will initiate records which will be maintained by Document Control to identify where the M&TE was used, identification of the measuring or test equipment calibrated, traceability to the calibration standard used for calibration, calibration data, identification of the individual performing the calibration. QA will perform independent assessments to verify implementation of the M&TE program.

2.7 M&TE will be controlled using approved procedures developed by Construction and Operations for their respective phase of project activities. The QA organization will review the procedures for the control of M&TE to ensure that the policy requirements are incorporated into the procedures.

# 3 Policy

## 3.1 General

3.1.1 M&TE requiring calibration shall include instruments or equipment used for testing, inspection, calibration of other instruments, process verification, or data collection for purposes of determining compliance with requirements.

3.1.2 Tools, gauges, instruments, and other measuring and test equipment used for activities affecting quality shall be properly handled and stored, calibrated at specific intervals, adjusted, and maintained to required accuracy limits.

3.1.3 Selections of M&TE shall be controlled to ensure that such items are of a proper type, range, accuracy, and tolerance to accomplish the function of determining conformance to requirements.

3.1.3.A Note: Calibration implementing documents may be based on the requirements contained in the following calibration program standards and meet the requirements of this policy.

3.1.3.A.1. ANSI/NCSL Z540-1-1994, American National Standard for Calibration-Calibration Laboratories and Measuring and Test Equipment-General Requirements.

3.1.3.A.2. ANSI N323A-1997, American National Standard for Radiation Protection Instrumentation Test and Calibration, Portable Survey Instruments.

## 3.2 Calibration

3.2.1 M&TE, including equipment that contains software or programmable hardware, shall be calibrated, adjusted, and maintained as a unit at prescribed intervals, software changes, or prior to use, against reference calibration standards having traceability to nationally

recognized standards. If no nationally recognized standard or physical constants exist, the basis for calibration shall be documented.

3.2.2 For M&TE used in one-time-only applications, the calibration shall be done both before and after use.

3.2.3 Calibration standards shall have a greater accuracy than the required accuracy of the M&TE being calibrated.

3.2.3.A If calibration standards with a greater accuracy than required of the M&TE being calibrated do not exist or are unavailable, calibration standards with accuracy equal to the required calibration accuracy may be used if they can be shown to be adequate for the requirements.

3.2.3.B The basis for the calibration acceptance shall be documented and authorized by responsible management. The level of management authorized to perform this function shall be identified.

3.2.4 The method and interval of calibration for each device shall be defined, based on the type of equipment, stability characteristics, required accuracy, intended use, and other conditions affecting measurement control.

3.2.5 A calibration or calibration check shall be performed when the accuracy of calibrated M&TE is suspect.

3.2.6 Calibrated M&TE shall be labeled, tagged, or otherwise suitably marked or documented to indicate due date or interval of the next calibration.

3.2.7 Calibrated M&TE shall be uniquely identified to provide traceability to its calibration data.

3.2.8 Updates to software contained in M&TE that affect calibration requires re-calibration of the equipment prior to use.

## 3.3 Documenting the Use of Measuring and Test Equipment

3.3.1 The use of M&TE shall be documented. The documentation shall identify the processes monitored, data collected, or items inspected or tested since the last calibration.

## 3.4 Out-of-Calibration Measuring and Test Equipment

3.4.1 M&TE shall be considered to be out-of-calibration and not be used until calibrated if any of the following conditions exist:

3.4.1.A The calibration due date or interval has passed without re-calibration.

3.4.1.B The device produces results known to be in error.

3.4.2 Out-of-calibration M&TE shall be controlled. The controls shall include the following requirements:

3.4.2.A Out-of-calibration M&TE shall be tagged, segregated, or otherwise controlled to prevent use until they have been recalibrated.

3.4.2.B When M&TE is found out of calibration during recalibration, the validity of results obtained using that equipment since its last valid calibration shall be evaluated.

3.4.2.B.1. The evaluation shall include the determination of acceptability for previously collected data, processes monitored, or items previously inspected or tested.

3.4.2.B.2. The evaluation shall be documented.

3.4.3 If any M&TE is consistently found out-of-calibration during the re-calibration process, it shall be repaired or replaced.

## 3.5 Lost Measuring and Test Equipment

3.5.1 When M&TE is lost, the validity of results obtained using that equipment since its last valid calibration shall be evaluated.

3.5.1.A The evaluation shall include the determination of acceptability for previously collected data, processes monitored, or items previously inspected or tested.

3.5.1.B The evaluation shall be documented.

## 3.6 Calibration Records

3.6.1 M&TE calibration documentation shall be maintained in accordance with Policy Q-17.1 – *Quality* Assu*rance Records,* and include the following information:

3.6.1.A Identification of the measuring or test equipment calibrated.

3.6.1.B Traceability to the calibration standard used for calibration.

3.6.1.C Calibration data.

3.6.1.D Identification of the individual performing the calibration.

3.6.1.E Identification of the date of calibration and the recalibration due date or interval.

3.6.1.F Results of the calibration and statement of acceptability.

3.6.1.G Reference to any actions taken in connection with out-of-calibration or nonconforming measuring and test equipment including evaluation results.

3.6.1.H Identification of the implementing document (including revision level) used in performing the calibration.

# 4 Specific DOE/RW-0333P QARD Requirements for IHLW Applications

4.1 All applicable DOE/RW-0333P QARD requirements have been included in Section 3 – *Policy.*

# 5 Records

5.1 No additional records requirements are applicable to this policy.

# 6 Responsibilities

## 6.1 All Personnel

6.1.1 Organizations using, calibrating, and maintaining M&TE, or procuring or requesting calibration services are responsible for implementing the requirements of this document as they apply to their functions.

## 6.2 Performing Organization Management (Operations/Construction)

6.2.1 Managers of affected organizations are responsible for implementation of adequate calibration programs and trained staff to meet the requirements of this policy.

## 6.3 Quality Assurance Manager

6.3.1 The QA Manager is responsible for reviewing M&TE calibration implementing documents.

# Policy Q-12.2 Installed Process Instrumentation

## 1 Purpose and Applicability

1.1 This policy defines requirements and responsibilities for control of installed process instrumentation used to support project processes and facility operations.

1.2 This policy is applicable as appropriate to project organizations responsible for the calibration, control or use of installed process instrumentation for applicable processes or systems, including procurement of instrumentation or calibration services.

## 2 Implementation Strategy

2.1 Installed Process Instrumentation (IPI) is the installed equipment used for monitoring of, or collecting data from, plant processes and facility operations and is an integral part of the process system. Procedures describing controls applicable to IPI will be established and implemented. The IPI is to be calibrated and maintained by trained workers in accordance with these procedures. The Operations Manager will define what equipment is considered IPI, and the calibration requirements are to be specified and documented in implementing procedures. Each piece of IPI is to be uniquely identified with the identification either placed on or near the individual piece of instrumentation or affixed on the instrumentation with a tag. The identification will be used for traceability and accountability of the equipment.

2.2 Calibration of the IPI is to be performed by trained individuals at specified intervals, commensurate with the application of the equipment. The calibration frequencies and accuracy requirements will be based on the system monitoring requirements, stability characteristics, service conditions, and other factors determined by Engineering and Operations. The measuring and test equipment described in Policy Q-12.1 – *Control of Measuring and Test Equipment,* will be used to calibrate the IPI.

2.3 IPI determined to be out of tolerance is to be documented and reported to the responsible management. An evaluation is required to determine the effect on the validity of previous data collected by that IPI, and the impact on previously accepted data. Conclusions for these evaluations, which indicate conditions adverse to quality, are to be documented and resolved in accordance with Policy Q-16.1 - *Corrective Action.*

2.4 The Operations Manager is responsible for developing the IPI procedures. The Quality Assurance (QA) organization will review the procedures for the control of IPI to ensure policy requirements are incorporated into the procedures.

## 3 Policy

### 3.1 General

3.1.1 Installed process instrumentation shall be controlled, calibrated, and administered using written procedures or instructions as appropriate.

**Policy Q-12.2 Installed Process Instrumentation**

3.1.2 Installed process instrumentation, including instrumentation that contains software or programmable hardware, shall be calibrated prior to initial use, against reference calibration standards having traceability to nationally recognized standards. If no nationally recognized standards exist the basis for calibration shall be documented.

3.1.3 Installed process instrument shall be re-calibrated at a prescribed schedule commensurate with application functions or functional classification.

3.1.4 Installed process instrumentation used to take measurements or readings to satisfy regulatory requirements shall be calibrated prior to initial use and re-calibrated at a prescribed schedule.

3.1.5 Calibration uncertainties of specified measuring and test equipment (M&TE) used to calibrate or verify installed process instrumentation calibrations shall be sufficiently small so that the accuracy of the measurement is not affected.

## 3.2 Identification and Control

3.2.1 Installed process instrumentation shall be uniquely identified. Where marking is not possible because of size, configuration, complexity, or location, the identification shall be affixed near the instrumentation to ensure that control is maintained.

3.2.2 Installed process instrumentation shall be labeled, tagged, or otherwise suitably marked, or documented to indicate calibration due date or interval of calibration due date or interval of calibration.

## 3.3 Calibration

3.3.1 Calibration of installed process instrumentation shall be performed by qualified individuals in accordance with Policy Q-02.2 - *Personnel Training and Qualification*.

3.3.2 Written and approved procedures or instructions shall be used to calibrate or verify calibration.

3.3.3 Calibration results shall be documented with sufficient detail to show traceability to nationally recognized standards.

## 3.4 Calibration Frequency

3.4.1 The calibration frequency shall be established and approved by the appropriate organization for installed process instrumentation. The initial calibration frequency shall be based on:

3.4.1.A Manufacturer's recommendation.

3.4.1.B Service conditions/functional classification.

3.4.1.C Instrumentation type and stability.

3.4.1.D Degree of use, accuracy, and reliability.

3.4.1.E Historical data, if available, for similar process instrumentation.

3.4.2 The calibration frequency may be adjusted with approval from the appropriate organization based on a review of previous calibration results, inherent stability, purpose of use, and accuracy required.

3.4.3 One-time calibration frequency extensions up to 25% of the established frequency is allowed with documented prior approval from the appropriate organization and Quality Assurance when necessary to support facility testing.

### 3.5 Out-of-Calibration Installed Process Instrumentation

3.5.1 Installed process instrumentation shall be considered out-of-calibration and not used until calibrated if any of the following exist:

3.5.2 The calibration due date or interval has passed without recalibration.

3.5.3 The instrument produces results known to be in error.

3.5.4 Out-of-calibration installed process instrumentation shall be controlled to prevent inadvertent use until it is recalibrated.

3.5.5 When installed process instrumentation is found out-of-calibration during recalibration, the validity of results obtained using the instrumentation since its last calibration shall be evaluated and documented.

3.5.6 If any installed instrumentation is consistently found to be out-of-calibration during the recalibration process, it shall be repaired or replaced as appropriate.

## 4 Specific DOE/RW-0333P QARD Requirements for IHLW Applications

4.1 All applicable DOE/RW-0333P QARD Requirements have been included in subsection 3 - *Policy*.

## 5 Records

5.1 Calibration records of installed process instrumentation shall include the following information as appropriate:

5.1.1 Identification of the instrumentation.

5.1.2 Traceability to the calibration standards.

5.1.3 Calibration data.

5.1.4 Identification of the individual performing the calibration.

5.1.5 Identification of the calibration date or internal as appropriate.

5.1.6 Results and acceptability of the calibration.

5.1.7 Reference to any actions taken to address out-of-calibration instrumentation including evaluation results, as appropriate.

5.1.8 Implementing documents used to perform the calibration.

# 6 Responsibilities

## 6.1 All Personnel

6.1.1 Organizations using, calibrating, and maintaining installed process instrumentation, or procuring or requesting calibration services are responsible for implementing the requirements of the policy as it applies to their functions.

## 6.2 Operations Manager

6.2.1 The Operations Manager is responsible for developing the implementing documents for this policy and providing adequate calibration program staff to meet the requirements of this policy.

## 6.3 Quality Assurance Manager

6.3.1 The QA Manager is responsible for reviewing implementing documents related to this policy.

# Policy Q-13.1 Handling, Storage, and Shipping

## 1 Purpose and Applicability

1.1 This policy identifies requirements and responsibilities for handling, storing, cleaning, packaging, shipping, housekeeping, and preserving items to prevent damage or loss and minimize deterioration.

1.2 This policy applies to organizations that handle, store, clean, package, ship, and preserve items.

## 2 Implementation Strategy

2.1 Procedures and other work controlling documents specific to a task are to be established and implemented to control the handling, storing, shipping, cleaning, and preservation of items to prevent damage, loss, or deterioration (i.e., loss of specified function.) The controls established for storing and shipping are to be derived from national consensus standards, or technical documents if no standards exist.

2.2 Instructions for marking and labeling for packaging, shipment, handling, and storage of items are to be established as necessary to adequately identify, maintain, and preserve item integrity, including indication of the need for special environments or special controls. Procedures for offsite transportation will be established and implemented. The requirements for special protective measures are to be documented. Measures may include special containers, shock absorbers, accelerometers, inert gas atmospheres, and controls on temperature and moisture levels. Such measures are also to be specified and provided, when required, to maintain acceptable item quality during storage.

2.3 Work control documents (procedures and instructions) must describe, as appropriate, the processes for the identification of items with unique requirements and specify the necessary protective methods for sensitive or perishable items, such as special handling, shipping, and storage controls for precision instrumentation and limited shelf-life items, and for items requiring special protective environmental controls, such as temperature and humidity controls.

2.4 The requirements and responsibilities for identifying and controlling items are specified in Policy Q-8.1 - *Identification and Control of Items*.

2.5 Work control documents for handling, storing and shipping, shall be developed based on the requirements of this policy.

## 3 Policy

### 3.1 General

3.1.1 The handling, storage, cleaning, packaging, shipping, housekeeping, and preservation of items shall be controlled to prevent damage or loss and to minimize deterioration. These activities shall be conducted in accordance with established work and inspection

instructions, drawings, specifications, shipping instructions, or other pertinent documents or procedures specified for use in conducting the activity.

3.1.2 When required for critical, sensitive, perishable, or high-value items, specific procedures for handling, storage, packaging, shipping, and preservation shall be used.

3.1.3 Housekeeping measures shall be established for control of work conditions and environments that can affect quality.

3.1.4 Enclosed systems shall be verified for cleanliness and exclusion of foreign material prior to closure of the system.

### 3.2 Special Equipment, Tools, and Environment

3.2.1 When required, special equipment (such as containers, shock absorbers, and accelerometers) and special protective environments (such as inert gas atmosphere, specific moisture content levels, and temperature levels) shall be specified and provided and their existence verified.

3.2.2 Special handling tools and equipment shall be utilized and controlled where necessary to ensure safe and adequate handling.

3.2.3 Special handling tools and equipment shall be inspected and tested periodically or prior to use as necessary to ensure performance.

3.2.4 Operators of special handling and lifting equipment shall be experienced or trained to use the equipment.

3.2.5 Special handling tools and equipment shall be inspected and tested at specified time intervals and in accordance with implementing documents to verify that the tools and equipment are adequately maintained.

### 3.3 Marking and Labeling

3.3.1 Measures shall be established for marking and labeling for the packaging, shipping, handling, and storage of items as necessary to adequately identify, maintain, and preserve the item.

3.3.2 Markings and labels shall indicate the presence of special environments or the need for special controls if necessary.

## 4 Specific DOE/RW-0333P QARD Requirements for IHLW Applications

4.1 All applicable DOE/RW-0333P QARD requirements are included in subsection 3 -*Policy*.

## 5 Records

5.1 No additional records requirements are applicable to this policy.

# 6 Responsibilities

## 6.1 Quality Assurance Manager

6.1.1 The QA Manager shall be responsible for monitoring the quality assurance program implementation for handling, storage, and shipping activities within the company.

## 6.2 Organizations

6.2.1 Organizations that generate procedures for the handling, storage, and shipping of items shall comply with the requirements contained in this policy.

6.2.2 Organizations involved in handling, storage, and shipping activities shall comply with applicable handling, storage, and shipping procedures.

# Policy Q-14.1 Inspection, Test and Operating Status

## 1 Purpose and Applicability

1.1 This policy identifies requirements and responsibilities associated with the use of status indicators to prevent inadvertent installation, use or operation of items.

1.2 This policy applies to organizations involved in controlling the inspection, test, and operating status of items during receipt inspection, construction, fabrication, operation, maintenance, and commissioning phases of facilities for which Bechtel National, Inc. (BNI) has responsibility.

## 2 Implementation Strategy

2.1 Managers of organizations that perform operating, support, or experimental functions are required to maintain physical status indicators and supporting documentation for those work processes that are under their control. Content, application, updating, or removal of physical status indicators will be controlled by procedure concurred with by the quality assurance (QA) organization and contain the requirements of this policy.

## 3 Policy

### 3.1 General

3.1.1 The status of inspection and test activities shall be identified either on the items or in documents traceable to the items where it is necessary to assure that required inspections and tests are performed, and to assure that items which have not passed the required inspections and tests are not inadvertently installed, used, or operated.

3.1.2 The use of status indicators shall be defined in implementing procedures.

### 3.2 Identification Methods

3.2.1 The identification methods shall preclude the inadvertent installation, use, or operation of items that have not passed required inspections and tests.

### 3.3 Identification of Status

3.3.1 Status shall be maintained through the use of legible and easily recognizable status indicators, such as physical location and tags, shop travelers, stamps, inspection or test records, or other suitable means.

3.3.2 Status indicators shall also provide for indicating the operating status of systems and components, such as by tagging valves and switches, to prevent inadvertent operation or changes in operating status.

### 3.4 Authority

3.4.1 The authority for application and removal of tags, markings, labels, and stamps shall be specified.

## 4 Specific DOE/RW-0333P QARD Requirements for IHLW Applications

4.1 All applicable DOE/RW-0333P QARD requirements are included in subsection 3 – *Policy*.

## 5 Records

5.1 No additional records requirements are applicable to this policy.

## 6 Responsibilities

### 6.1 Quality Assurance Manager

6.1.1 The QA Manager is responsible for establishing and maintaining a system for identifying the quality status of items, which includes, but is not limited to, acceptance, rejection, hold for inspection, and conditional use.

### 6.2 Performing Managers

6.2.1 Affected Managers are responsible for establishing and maintaining a system to control equipment and system operational status and equipment lock-out and tag-out.

### 6.3 Organizations Performing Inspection, Test, or Operating Activities

6.3.1 Organizations that perform inspections, tests, or operating activities are responsible for complying with the status indicator requirements described in this document and procedures that implement these requirements.

# Policy Q-15.1 Control of Nonconforming Items

## 1 Purpose and Applicability

1.1 This policy identifies requirements and responsibilities for controlling items that do not conform to specified requirements to prevent their inadvertent installation or use.

1.2 This policy applies to all Quality Level (Q) items, and items that are determined to be suspect/counterfeit items regardless of quality level.

1.3 The requirements identified in this policy are optional for the following items:

1.3.1 Nonconforming items discovered while in an in-process status under work process control procedures that are re-worked within the scope of the work process control to meet existing design requirements.

## 2 Implementation Strategy

2.1 Management's role in achieving quality includes promoting, supporting, and encouraging effective problem identification and correction. The individual worker's role will be to meet the quality requirements and to recommend improvements in item quality. All personnel will be granted the freedom and authority to identify those items determined to be adverse to quality, and as appropriate, to stop work or request that work be stopped until effective corrective action is completed. The Quality Assurance (QA) Manager is responsible for developing the processes to detect and correct quality problems.

2.2 Project procedure(s) will require personnel to report identified nonconforming items. Identification methods include inspecting, testing, auditing, surveillances, and worker observation. Project procedure(s) will require nonconforming items to be reported and documented using the Nonconformance Report (NCR). NCRs will be reported to the organization responsible for dispositioning and the QA organization for tracking and trending in the project electronic database. The nonconforming items procedure will require that items not meeting established requirements be identified, controlled, and corrected. Correction includes identifying the causes of problems and taking action to prevent recurrence. The extent of cause analysis for nonconforming items will be commensurate with the importance or significance of the problem.

2.3 Repetitive or significant problems with nonconforming items may require more extensive evaluation and analysis. When these conditions occur they are to be analyzed for root cause through the corrective action system (Policy 16.1 - *Corrective Action*) and documented. The corrective action system will require a root cause analysis, identification and implementation of steps necessary to prevent recurrence, and the reporting of results to senior project management. Implementation of the required corrective action is to be performed and documented by the responsible organization and verified by the QA organization. Nonconforming items that are subsequently re-worked, repaired, or replaced are to be inspected and/or tested to either the original requirements or to specified alternative requirements. Such inspections or tests are to be conducted before the final acceptance of the item. Refer to Policy 11.1 - *Test Control* for the requirements for testing items.

2.4 Engineering is chartered with having an adequate technical understanding of the work, access to pertinent background information, and will be responsible for the analysis and disposition of nonconformances involving "Repair" or "Use-As-Is" dispositions.

2.5 QA/QC activities associated with nonconforming items will include validation of the nonconformance, review of dispositions, verification of completion of disposition actions, and closure of the reporting document.

2.6 The nonconforming items procedure will be developed by the QA organization based on the following requirements of this policy.

# 3 Policy

## 3.1 General

3.1.1 Items that do not conform to specified requirements shall be controlled to prevent inadvertent installation or use of the item. Controls shall provide for identification, documentation, evaluation, segregation when practical, and disposition of nonconforming items, and for notification to relevant organizations.

3.1.2 QA/QC activities associated with nonconforming items shall include validation of the nonconformance, review of dispositions, verification of completion of disposition actions, and closure of the reporting document.

## 3.2 Documentation and Evaluation

3.2.1 Nonconformance documentation shall clearly identify and describe the characteristics that do not conform to specified criteria.

3.2.2 Nonconforming items shall be evaluated, and recommended dispositions shall be proposed, evaluated, and approved.

3.2.3 The review shall include determining the need for corrective action according to the requirements of Policy Q-16.1 - *Corrective Action*.

3.2.4 Documentation of a nonconformance is required when a Q item:

3.2.4.A Fails to meet required technical or quality requirements.

3.2.4.B Is of indeterminate quality.

3.2.4.C Is a suspect/counterfeit item.

3.2.4.D Has documentation deficiencies (i.e., missing, incomplete, illegible, or damaged documents, improper revisions; or documents having unauthorized changes) which render the quality of the item indeterminate and which cannot be corrected before further processing, delivery, installation, or use.

### 3.3 Notification

3.3.1 Organizations affected by the nonconformance shall be notified.

### 3.4 Personnel

3.4.1 Personnel performing evaluations to determine a disposition shall have demonstrated competence in the specific area they are evaluating, have adequate understanding of the requirements, and have access to pertinent background information.

### 3.5 Responsibility and Authority

3.5.1 The responsibility and authority for reviewing, evaluating, approving the disposition, and closing nonconformances shall be defined.

3.5.2 Responsibility for the control of further processing, delivery, installation, or use of nonconforming items shall be designated in writing.

3.5.3 Further processing, delivery, installation, or use of a nonconforming item shall be controlled pending the evaluation and an approved disposition by authorized personnel.

### 3.6 Identification

3.6.1 Nonconforming items shall be identified by marking, tagging, segregation, or other methods not detrimental to the item, the container, or the package containing the item. The identification shall be legible and easily recognizable.

3.6.2 If the identification of a nonconforming item is not practical, then the container, package, or segregated storage area, as appropriate, shall be identified.

### 3.7 Segregation

3.7.1 Nonconforming items shall be segregated, when practical, by placing them in a clearly identified and designated hold area until properly dispositioned.

3.7.2 When segregation is impractical or impossible due to physical conditions such as size, weight, or access limitations, other precautions shall be employed to preclude inadvertent use of the nonconforming item.

### 3.8 Disposition

3.8.1 The disposition of use-as-is, reject, repair, or re-work for nonconforming items shall be identified and documented.

3.8.2 The technical justification for the acceptability of a nonconforming item that has been dispositioned repair or use-as-is shall be documented.

3.8.3 Items that do not meet original design requirements that are dispositioned use-as-is or repair shall be subject to design control measures commensurate with those applied to the original design.

3.8.4 Required as-built records shall reflect the use-as-is or repair condition.

3.8.5 If changes to the specifying document are required to reflect the as-built condition, then the disposition shall require action to change the specifying document to reflect the accepted nonconformance.

3.8.6 Any document or quality assurance record change required by the disposition of the nonconformance shall be identified in the nonconformance documentation; and, when each document or record is changed, the justification for the change shall identify the nonconformance documentation.

3.8.7 The disposition of an item to be re-worked, or repaired shall contain a requirement to re-examine (inspect, test), or nondestructively examine the item to verify acceptability.

3.8.8 The recommended disposition shall be evaluated and approved.

### 3.9 Re-examination

3.9.1 Repaired or re-worked items shall be reexamined using the original process and acceptance criteria unless the nonconforming item disposition has established alternate acceptance criteria.

### 3.10 Quality Trending

3.10.1 Nonconformance documentation shall be at a minimum quarterly analyzed by the QA organization to identify quality trends in accordance with Policy Q-16.1 - *Corrective Action.*

## 4 Specific DOE/RW-0333P QARD Requirements for IHLW Applications

4.1 All applicable DOE/RW-0333P QARD requirements are included in subsection 3 – *Policy.*

## 5 Records

5.1 NCRs and associated documentation are considered quality records to be maintained in accordance with Policy Q-17.1 - *Quality Assurance Records*.

## 6 Responsibilities

### 6.1 Quality Assurance Manager

6.1.1 The QA Manager or designee is responsible for establishing the procedure(s) for definition, implementation, and maintenance of the process for the control of nonconforming items. They are also responsible for:

6.1.1.A Validation of nonconformances.

6.1.1.B Reviewing and concurring with conditional use evaluations.

6.1.1.C Review of nonconformance dispositions.

6.1.1.D Performing verification of implemented corrective actions.

6.1.1.E Ensuring that quality nonconformance control status tags are applied and removed as appropriate.

6.1.1.F Closure of nonconformances.

## 6.2 Manager of Engineering

6.2.1 The Manager of Engineering is responsible for establishing processes to control the analysis and disposition of nonconformances involving "Repair" or "Use-As-Is" dispositions.

## 6.3 All Managers

6.3.1 Each manager is responsible and accountable for ensuring that:

6.3.1.A Ensuring procedures relating to the nonconforming item process are effectively implemented.

6.3.1.B Promoting an open environment and culture to support the identification and resolution of nonconforming items so that employees may report nonconformances without fear of reprisal.

6.3.1.C Ensuring that nonconforming items under their purview are identified, documented, and resolved in an effective and timely manner.

6.3.1.D Using designees to implement many of the activities to resolve nonconforming items and to ensure that adequate priority and resources are allocated for effective process implementation.

6.3.1.E Performing categorization and ensuring the completion of applicable reportability reviews and operability evaluations, as required, for nonconforming items.

6.3.1.F Ensuring nonconforming items are properly tagged or segregated to prevent inadvertent installation or use.

6.3.1.G Ensuring that nonconforming items that pose a threat to employee safety or health, or represents an imminent threat to the environment, the public or property are placed in a safe condition and that an evaluation is conducted to determine if stopping work is warranted.

## 6.4 All Personnel

6.4.1 All personnel are responsible for identifying and reporting items that could be categorized as nonconforming.

# Policy Q-15.2 Control of Suspect/Counterfeit Items

## 1 Purpose and Applicability

1.1 This policy identifies requirements and responsibilities for identifying, analyzing, and dispositioning Suspect/Counterfeit Items (S/CI) and preventing S/CIs from being supplied through the collection, analysis, and dissemination of S/CI information.

1.2 This policy applies to all Important to Safety Systems, Structures, and Components (SSC), critical load path of hoisting and rigging equipment, non-ITS SSCs where the introduction of S/CI would have a great potential for creating unsafe conditions, and worker industrial safety items.

## 2 Implementation Strategy

2.1 Suspect/Counterfeit Items will be prevented from being introduced or used through the involvement of Engineering, Safety Assurance, Construction, design, procurement, testing, inspection, maintenance, evaluation, disposition, reporting, trend analysis, and lessons learned work process controls.

2.2 Controls will ensure that the uses of S/CIs are restricted to only those items that have been found acceptable through engineering analysis and a formal disposition process.

## 3 Policy

### 3.1 General

3.1.1 Management shall regularly assess the adequacy and effective implementation of their S/CI processes. Problems that hinder the organization from achieving its objectives shall be identified and corrected.

3.1.2 Procedures that implement the S/CI program shall be in place and followed.

### 3.2 S/CI Items of Concern

3.2.1 A listing of Suspect/Counterfeit Items of concern shall be developed, maintained, and disseminated. The list shall be updated by reviewing applicable source documents including:

3.2.1.A Government Industry Data Exchange Program (www.gidep.org)

3.2.1.B Institute of Nuclear Power Operations (www.inpo.org)

3.2.1.C DOE Occurrence Reporting and Processing System

3.2.1.D DOE S/CI website (http://tis.eh.doe.gov/paa/sci/)

## 3.3 Identification and Control

3.3.1 Controls shall provide for identification, inspection, documentation, evaluation, segregation when practical, notification of relevant organizations, and disposition of S/CIs installed in all safety applications and other applications that create potential hazards.

3.3.2 Controls shall provide for engineering involvement in the development of procurement specifications; during inspection and testing; and when replacing, maintaining, or modifying equipment. Engineering evaluations must consider potential risks to the public and workers, cost/benefit impact, and a schedule for replacement (if required).

3.3.3 Controls shall assure that inventory and storage areas are periodically inspected to identify S/CIs.

3.3.4 Controls shall ensure that S/CIs identified in non-safety applications during routine maintenance and/or inspection are reported, evaluated, and dispositioned to prevent future use in safety applications.

3.3.5 Controls shall ensure that S/CIs identified by WTP personnel are reported to responsible DOE ORP line management.

3.3.6 Controls shall ensure that the DOE Office of Inspector General (OIG) is contacted before S/CIs and their documentation are destroyed or disposed of. The OIG determines whether to retain them for criminal investigation or litigation.

3.3.7 Controls shall ensure that the uses of S/CIs are restricted to only those items that have been found acceptable through engineering analysis and a formal disposition process.

3.3.8 Controls shall include the use of trend analysis and lessons learned reports for improving the S/CI process.

## 3.4 Testing

3.4.1 Controls shall ensure that procured or installed S/CIs are tested as necessary using approved engineering test methods.

## 3.5 Training

3.5.1 Appropriate personnel shall receive initial and continuing S/CI training.

3.5.2 Appropriate personnel shall be trained and informed of S/CI processes and controls (including prevention, detection, and disposition of S/CIs).

## 3.6 Records

3.6.1 All records designated in implementing documents as quality assurance records shall be controlled in accordance with Policy Q-17.1 - *Quality Assurance Records*.

# 4 Specific DOE/RW-0333P QARD Requirements for IHLW Applications

4.1 All applicable DOE/RW-0333P QARD requirements have been included in subsection 3 – *Policy*.

# 5 Responsibilities

## 5.1 Management

5.1.1 All levels of management are responsible for implementation of the S/CI program by participating in the prevention and control of S/I process.

5.1.2 Managers are responsible for, using the graded approach, the training of employees involved with S/CI controls, which include the prevention, detection, and disposition methods used by the WTP.

## 5.2 Quality Assurance Manager

5.2.1 The QA Manager, or designee, is responsible for serving as the point of contact responsible for S/CI activities to ensure that the DOE Office of Environment, Safety and Health has a viable recipient for S/CI information notices. The QA Manager, or designee, is responsible for establishing the procedure(s) for definition, implementation, and maintenance of the process for the prevention and control of S/CIs. They or their designee are also responsible for:

5.2.1.A Developing and maintaining a listing of Suspect/Counterfeit Items of concern.

5.2.1.B Dissemination of S/CI information.

5.2.1.C Providing notification to project management of S/CIs that may affect the project.

5.2.1.D Conducting assessments to ensure that S/CI controls are in place and effective.

## 5.3 Quality Control Manager

5.3.1 The Quality Control Manager is responsible for serving as the Point of Contact for OIG notifications.

5.3.2 The Quality Control Manager is responsible for providing notification to the Department of Energy of S/CIs and potential S/CIs.

## 5.4 Manager of Engineering

5.4.1 The Manager of Engineering is responsible for preventing the introduction and use of S/CIs, for permanent plant equipment, through engineering involvement in the design, procurement, testing, inspection, maintenance, evaluation, and disposition of S/CI information.

5.4.2 The Manager of Engineering is responsible for establishing processes to control the engineering analysis and formal disposition process for the use of S/CIs.

### 5.5 Safety Assurance Manager

5.5.1 The Safety Assurance Manager is responsible for preventing the introduction and use of S/CIs, for industrial safety related items, through involvement in design, procurement, testing, inspection, maintenance, evaluation, and disposition of S/CI information.

### 5.6 Manager of Construction

5.6.1 The Manager of Construction is responsible for preventing introduction of S/CI, for non-permanent plant equipment, through involvement in design, procurement, testing, inspection, maintenance, evaluation, and disposition of S/CI information.

### 5.7 All Personnel

5.7.1 All personnel are responsible for identifying and reporting items that could be categorized as suspect/counterfeit items.

# Policy Q-16.1 Corrective Action

## 1 Purpose and Applicability

1.1 This policy identifies requirements and responsibilities for ensuring that conditions adverse to safety, health, operations, quality, security, and the environment are promptly identified, controlled, and corrected as soon as practical through the corrective action system.

1.2 This policy applies to all organizations responsible for achieving, maintaining, and verifying the quality of items, services, and activities of facilities, programs, and projects; and to those corresponding conditions that may be adverse to safety, health, operations, quality, security, and the environment.

1.3 This policy applies to conditions identified by external agencies and by employees in performance of their routine duties including internal independent audits, surveillances, and management assessments.

## 2 Implementation Strategy

2.1 One fundamental element of continuous improvement is the corrective action system. The objective of a corrective action system is to identify, control, document, evaluate, and trend conditions adverse to quality, and to develop and implement appropriate actions to correct the adverse condition. The corrective action system is a vital tool for implementing the continuous improvement element of the quality assurance program. Quality improvement is the essence of the feedback and improvement core function of Integrated Safety Management.

2.2 Project management will have the responsibility to achieve quality in the products produced and services provided. Management's role includes promoting the corrective action system, and supporting and encouraging effective problem identification and correction. The individual worker's role will be to meet the quality requirements and to recommend improvements in service and process quality. All personnel have the authority and are encouraged to identify those services, and processes determined to be adverse to quality, and as appropriate, to stop work or request that work be stopped until effective corrective action is completed. The Quality Assurance (QA) Manager is responsible for developing the processes to detect and prevent quality problems.

2.3 Services and processes that do not meet established requirements are to be identified (through a variety of methods including assessments, audits, surveillances, and worker observations), documented, controlled, and corrected according to the importance of the problem and the work affected. Correction includes identifying the causes of problems and taking appropriate corrective action.

2.4 For conditions adverse to quality the condition will be documented, reported to responsible management, and corrected in an efficient and timely manner based on the nature and complexity of the problem. The condition adverse to quality will be tracked and trended by the QA organization using an electronic database.

2.5 Significant conditions adverse to quality (a subset of conditions adverse to quality) will be identified using a risk-based approach with criteria related to repetitive problems, adverse

trends, and impacts or consequences associated with personnel safety and health, the environment, and project milestones including cost and schedule. When these conditions occur they are to be analyzed for the root cause and identification of steps necessary to prevent recurrence. Significant conditions adverse to quality will be reported to senior project management. Determination of root cause will be based on guidance available in commercial industry standards. Commercial industry root cause methods include event and causal factor charting, barrier analysis, and the "Why" Stair Case, each is applied as appropriate to the nature and complexity of the significant condition adverse to quality. Implementation of the required corrective action(s) is to be performed, documented, and verified by the responsible organization. Lessons learned from the corrective action process are shared with management to foster the prevention of recurrence.

2.6 Continuous improvement objectives are to be met by measuring and evaluating performance against key performance indicators/standards. Examples include repeat problems, timeliness of actions, trending in the number of deficiencies, and trends related to causes. Item characteristics, process implementation, and other quality-related information are to be reviewed as necessary, and the data analyzed to identify improvement opportunities and potential problem areas before they become significant. This data is to be used to identify trends that adversely impact quality and opportunities to improve items and processes. Data will be collected from a variety of sources such as management assessments, external audits, independent audits, surveillances, deficiency reports, and nonconformance reports. After data analysis, at a minimum, quarterly reports will be issued to senior management who has the responsibility to effect the changes they deem necessary.

2.7 The QA organization is responsible for developing the necessary project procedures that implement this policy based on the requirements of this policy.

# 3 Policy

## 3.1 General

3.1.1 Conditions adverse to quality are those conditions where a stated non-compliance with a QA requirement exists, or an implementing document requirement is not met. The general requirements for correcting conditions adverse to quality include:

3.1.1.A Classification of the condition as conditions adverse to quality or significant conditions adverse to quality.

3.1.1.B Conditions adverse to quality shall be identified promptly and corrected as soon as practical.

3.1.1.C In the case of significant conditions adverse to quality (a subset of conditions adverse to quality), the cause shall be determined and corrective action taken to preclude recurrence.

3.1.1.D The identification of, cause and corrective action for significant conditions adverse to quality shall be documented and reported to appropriate levels of management.

3.1.1.E Follow-up action shall be taken to verify implementation of corrective action.

3.1.2 QA management shall retain the right to initiate a stop work order for significant conditions adverse to quality in any project activity.

## 3.2 Conditions Adverse to Quality

3.2.1 Responsible management shall perform investigative action to determine the extent of the adverse conditions and complete remedial action as soon as practical.

3.2.2 Conditions adverse to quality shall be documented and reported to appropriate levels of management responsible for the conditions and to the QA organization for tracking and trending.

## 3.3 Significant Conditions Adverse to Quality

3.3.1 Criteria for determining significant conditions adverse to quality shall be established and identified.

3.3.2 The identification, cause, and corrective action for significant conditions adverse to quality shall be documented and reported to appropriate levels of management responsible for the organization and to the QA organization for tracking.

3.3.3 Responsible management shall:

3.3.3.A Perform investigative action to determine the extent and impact of the conditions and document the results.

3.3.3.B Determine, document, and complete remedial action as soon as practical.

3.3.3.C Determine and document the root cause using formal root cause techniques.

3.3.3.D Identifying and implementing corrective actions that will preclude recurrence as soon as practical.

## 3.4 Follow-up and Closure Action for Conditions Adverse to Quality

3.4.1 Completion of corrective actions shall be verified.

3.4.2 Follow-up management assessments, surveillances, or independent audits should be scheduled after verifying implementation of corrective actions to determine the effectiveness of the corrective actions. The need for follow-up evaluations is determined in accordance with the implementing procedure.

## 3.5 Quality Trending

3.5.1 The QA organization shall establish criteria for determining adverse quality trends using appropriate techniques.

3.5.2 Reports of nonconformance and conditions adverse to quality shall be evaluated to identify adverse quality trends and help identify root causes.

3.5.3 Trend evaluation shall be performed at a minimum quarterly, and in a manner that provides for prompt identification of adverse quality trends.

3.5.4 Trend evaluations shall be distributed to the Project Director, Project Manager and management of impacted organizations.

3.5.5 Identified adverse trends shall be reported to the management of the organization responsible for corrective action.

## 3.6 Conditions Adverse to Industrial Safety and Health

3.6.1 Responsible management shall perform investigative action to determine the extent of the adverse conditions and complete remedial action as soon as practical.

3.6.2 Conditions adverse to safety and health shall be documented and reported to appropriate levels of management responsible for the conditions and to the Safety Assurance organization for tracking.

## 3.7 Significant Conditions Adverse to Industrial Safety and Health

3.7.1 Criteria for determining significant conditions adverse to safety and health shall be established and identified.

3.7.2 The identification, cause, and corrective action for significant conditions adverse to safety and health shall be documented and reported to appropriate levels of management responsible for the organization and to the Safety Assurance organization for tracking.

3.7.3 Responsible management shall:

3.7.3.A Perform investigative action to determine the extent and impact of the conditions and document the results.

3.7.3.B Determine, document, and complete remedial action as soon as practical.

3.7.3.C Determine and document the root cause using formal root cause techniques.

3.7.3.D Identify and implement corrective actions that will preclude recurrence as soon as practical.

## 3.8 Follow-up and Closure Action for Conditions Adverse to Industrial Safety and Health

3.8.1 Completion of corrective actions shall be verified.

3.8.2 Follow-up management assessments or surveillances should be scheduled after verifying implementation of corrective actions to determine the effectiveness of the corrective actions. The need for follow-up evaluations is determined in accordance with the implementing procedure.

# 4 Specific DOE/RW-0333P QARD Requirements for IHLW Applications

In addition to the requirements found in section 3 of this Policy, the following requirements are applicable to High Level Waste activities and shall be implemented.

## 4.1 Conditions Adverse to Quality

4.1.1 The QA organization shall concur with the proposed remedial action to ensure that QA program requirements are satisfied.

## 4.2 Significant Conditions Adverse to Quality

4.2.1 Significant conditions adverse to quality shall be evaluated for a stop work condition by the QA organization to determine if a stop work order is warranted.

4.2.2 QA management shall issue stop work orders to responsible management after a stop work condition has been identified.

4.2.3 The QA organization shall concur with the proposed corrective action, including remedial action, the root cause, and actions taken to prevent recurrence, to ensure that QA program requirements are satisfied.

4.2.4 QA management shall take appropriate action to lift and close (in part or total) the stop work issued by the QA organization based on the resolution of the related significant condition adverse to quality.

## 4.3 Follow-Up

4.3.1 The QA organization shall verify implementation of corrective actions taken for all reported conditions adverse to quality and close the related corrective action documentation in a timely manner when actions are complete.

# 5 Records

5.1 All records designated in implementing documents as quality assurance records. Shall be controlled in accordance with Policy Q-17.1 - *Quality Assurance Records.*

# 6 Responsibilities

## 6.1 Quality Assurance Manager

6.1.1 The QA Manager is responsible for the following:

6.1.1.A Review and concurrence of procedures for reporting and controlling conditions adverse to quality in accordance with the requirements of this policy.

6.1.1.B Concurring with causal analysis and corrective action plans as required.

6.1.1.C Verifying implementation of corrective actions as required.

6.1.1.D Trending conditions adverse to quality.

6.1.1.E Evaluating conditions adverse to quality to determine reportability and Price-Anderson Amendment Act (PAAA) compliance.

## 6.2 Managers

6.2.1 Managers are responsible for ensuring that conditions adverse to quality are identified and controlled in accordance with approved procedures and for ensuring that an atmosphere is created in the workplace where reporting and resolution of conditions adverse to quality is encouraged at all levels.

## 6.3 All Personnel

6.3.1 All personnel are responsible for identifying, documenting and reporting potential conditions adverse to quality.

# Policy Q-16.2 Stop Work

## 1 Purpose and Applicability

1.1 This policy defines the requirements for stopping work and provides a mechanism for any employee to identify quality problems.

1.2 This policy applies to all personnel working at or for the project.

## 2 Implementation Strategy

2.1 An important attribute of integrated safety management is the ability of any project employee to stop work when such work presents an imminent danger to their safety or health, the environment, facilities or property. Project management is responsible for ensuring the safety of employees and for taking appropriate actions to correct the cause(s) for stopping work. Procedure(s) for implementing the stop work process will be developed by the quality assurance (QA) organization that contain the requirements of this policy.

## 3 Policy

### 3.1 General

3.1.1 The project empowers employees to stop work when a concern presents an imminent danger to employee safety and health, the environment, facilities, or property.

3.1.2 A stop work is initiated through the Project Manager for office work and the Construction or Operations Manager for site activities.

3.1.3 The following are typical situations in which work stoppage may be initiated.

3.1.3.A Other corrective action processes are ineffective in protecting the health and safety of the public and/or plant personnel.

3.1.3.B Continued work will require significant rework or repair to backfit corrective action.

3.1.3.C An organization, department, group, sections, or individual by a repetitive failure to comply with technical or administrative controls contributes to a condition that is a significant QA program deficiency.

3.1.3.D An uncontrolled chemical spill or radioactive release has occurred or is imminent.

3.1.4 Significant conditions adverse to quality shall be evaluated for a stop work condition by the management to determine if stopping work is warranted.

3.1.5 Management shall take appropriate action to lift and close (in part or total) the stop work based on the actions taken to address the significant condition adverse to quality.

3.1.6 QA management shall initiate a stop work order when conditions identified warrant a stoppage of work.

3.1.7 For stop work conditions initiated by QA management, only QA management shall take appropriate action to lift and close (in part or total) the stop work order based on the actions taken to address significant condition adverse to quality.

# 4 Specific DOE/RW-0333P QARD Requirements for IHLW Applications

4.1 All applicable DOE/RW-0333P QARD requirements are included in Section 3 – *Policy*.

# 5 Records

5.1 No additional records requirements are applicable to this policy.

# 6 Responsibilities

## 6.1 Project Director

6.1.1 The Project Director is responsible for stopping applicable work activities when conditions warrant stoppage.

## 6.2 Performing Managers (Construction and Operations)

6.2.1 Affected managers are responsible for stopping applicable work activities when conditions warrant work stoppage.

## 6.3 Quality Assurance Manager

6.3.1 The QA Manager is responsible for issuing a work stoppage when conditions identified warrant the stoppage of work.

## 6.4 All Personnel

6.4.1 All employees have a responsibility to notify the supervisor when a concern presents an imminent danger to employee safety and health, the environment, facilities, or property and to stop the activity if warranted.

# Policy Q-17.1 Quality Assurance Records

## 1 Purpose and Applicability

1.1 This policy identifies requirements and responsibilities for identifying, administrating, and temporarily storing documents and construction records designated as quality assurance (QA) records.

1.2 This policy applies to project personnel who prepare or process documents designated as QA records per Policy Q-06.1 – *Document Control.*

1.2.1 Note: The term "records' used throughout this section, is to be interpreted as *quality assurance* records.

## 2 Implementation Strategy

2.1 A document becomes a record when it is completed and validated. Records, sufficient to provide objective evidence of the quality of an item or activity, and if necessary, to support technical and regulatory decisions, will be identified and used for activities affecting completed work. Records are to be specified in documents affecting quality, and prepared, reviewed, approved, and maintained using a graded approach. Record maintenance will include provisions for record retention, protection, personnel access control, preservation, traceability, accountability, and retrievability. Quality-affecting implementing procedures are to identify which records must be maintained and controlled as a record. Records are to be stored as hard copy, microfilm, magnetic media, or on optical disks. Records requiring special processing and control, such as computer codes or information on high-density media or optical disks are to be controlled to ensure their validity and usability. Hardware and software needed to maintain and access these records will also require control to ensure their retrievability and readability.

2.2 Project document control facilities are to be used for records storage. The project may also use staging areas for records wherein records are indexed and prepared for transfer to project document control. Staging areas are to be equipped with fire detection and suppression devices and include provisions for controlling access to the records. All of these areas will provide retention, protection, preservation, traceability, accountability, and retrievability of records.

2.3 The Deputy Project Manager is responsible for developing the procedures implementing the requirements of this policy that will be concurred with by the QA organization.

## 3 Policy

### 3.1 General

3.1.1 Records shall furnish documentary evidence that items or activities meet specified quality requirements.

3.1.2 Records shall be identified, generated, authenticated, maintained, and their final disposition specified. Requirements and responsibilities for these activities shall be documented.

3.1.3 A project records system shall be maintained and enforced in accordance with written procedures, instructions, or other documentation.

3.1.4 Requirements and responsibilities for record transmittal, distribution, retention, maintenance, and disposition shall be established and documented.

3.1.5 Records shall be distributed, handled, and controlled in accordance with written procedures.

## 3.2 Generation of Records

3.2.1 Records shall be legible and identifiable.

3.2.2 Records shall be traceable to associated items and activities and accurately reflect the work accomplished or information required.

3.2.3 Individuals handling records shall protect them from damage or loss until the records are submitted to the records management system.

3.2.3.A Note: Records may be originals or copies.

3.2.4 Implementing documents shall:

3.2.4.A Identify those documents that will become records.

3.2.4.B Identify the organization responsible for submitting the records to the records management system.

3.2.5 Individuals creating records shall ensure that the records are legible, accurate, complete, appropriate to the work accomplished, and identifiable to the item(s) or activity(s) to which they apply.

## 3.3 Authentication of Records

3.3.1 Documents shall be considered valid records only if stamped, initialed, or signed and dated by authorized personnel or otherwise authenticated.

3.3.2 If the nature of the record (such as magnetic or optical media) precludes stamping, initialing or signing, then other means of identifying the record as complete by authorized personnel are permitted.

## 3.4 Classification of Records

3.4.1 Records shall be classified as lifetime or nonpermanent.

3.4.2 Lifetime records are those that meet one or more of the following criteria:

3.4.2.A Those which would be of significant value in demonstrating capability for safe operation.

3.4.2.B Those which would be of significant value in maintaining, reworking, repairing, replacing, or modifying an item.

3.4.2.C Those which would be of significant value in determining the cause of an accident or malfunction of an item.

3.4.2.D Those which would provide required baseline data for in-service inspections.

3.4.2.E Project personnel exposure records.

3.4.2.F Documents which are implementing documents as described in Policy Q-05.1 - *Instructions, Procedures and Drawings* shall be classified as nonpermanent records.

3.4.3 Documents that do not meet the requirements for lifetime records, but provide evidence that the QA program has been properly executed shall be classified as nonpermanent records.

3.4.3.A Note: Nonpermanent records are those records required to show evidence that an activity was performed in accordance with the applicable requirements but need not be retained for the life of the item because they do not meet the criteria for lifetime records.

## 3.5 Receipt Control of Records

3.5.1 The organization responsible for the receipt of records shall designate a person or position responsible for receiving records.

3.5.2 The designee shall be responsible for organizing and implementing a system of receipt control of records for temporary storage including a method for verifying that the records are those designated.

3.5.3 Records shall be protected from damage, deterioration, or loss when received.

3.5.4 Legibility and completeness of records shall be verified.

3.5.5 As a minimum, a receipt control system shall include:

3.5.5.A A method for designating the required records.

3.5.5.B A method for identifying records received.

3.5.5.C Procedures for receipt and inspection of incoming records.

3.5.6 The receipt control system shall be structured to permit a current and accurate assessment of the status of records during the receiving process.

## 3.6 Storage of Records

3.6.1 Records shall be stored in facilities, containers, or a combination thereof, constructed and maintained in a manner which minimizes the risk of damage or destruction from the following:

3.6.1.A Natural disasters such as winds, floods, or fires.

3.6.1.B Environmental conditions such as high and low temperatures and humidity.

3.6.1.C Infestation of insects, mold, or rodents.

3.6.2 The storage arrangement shall provide adequate protection of special processed records (e.g., photographs, negatives, microfilm, and magnetic media) to preclude damage from moisture, temperature, excessive light, electromagnetic fields, or stacking, consistent with the type of record being stored.

3.6.3 The storage area shall be protected from unauthorized entry, larceny, and vandalism.

3.6.4 Storage of records by the authenticating organization prior to transfer to a central file location shall minimize the risk of loss, damage, or destruction. As a minimum, records shall be stored and indexed for retrievability within a facility or container. The containers or facilities shall bear an Underwriter's Laboratories label (or equivalent) certifying 1-hour fire protection, or be certified by a person competent in the technical field of fire protection.

3.6.5 Records shall be stored and preserved in predetermined storage facilities in accordance with an approved implementing procedure that provides:

3.6.5.A A description of the storage facility.

3.6.5.B A description of the filing system to be used.

3.6.5.C A method for verifying that the records received are in agreement with the transmittal document.

3.6.5.D A description of controls governing record access, retrieval, and removal.

3.6.5.E A method for filing supplemental information.

3.6.5.F A method for disposition of superseded records.

3.6.6 If a single facility, container, or combination is not capable of providing adequate protection, dual facilities, containers, or combination shall be provided for record storage at locations sufficiently remote from each other to eliminate the chance of exposure to a simultaneous hazard.

3.6.6.A Note: Dual storage facilities are not required to meet the design and construction requirements specific for a long-term single storage facility.

3.6.7 Storage methods shall be developed to preclude deterioration of records. Approved filing methods shall require records to be firmly attached in binders or placed in folders or envelopes for storage in steel file cabinets or on shelving in containers appropriate for the record medium being stored.

## 3.7 Retention and Disposition of Records

3.7.1 QA record retention periods shall be documented.

3.7.2 Records shall be maintained for their retention periods.

3.7.3 Lifetime records are required to be maintained by or for the plant owner for the life of the particular item while it is installed in the plant or stored for future use.

3.7.4 Nonpermanent records shall not be disposed of until the following conditions are met:

3.7.4.A Regulatory requirements are satisfied.

3.7.4.B Operational status permits.

3.7.4.C Purchaser's requirements are satisfied, or a minimum of three years whichever is longer.

## 3.8 Retrieval of Records

3.8.1 Records shall be retrievable.

3.8.2 Records shall be indexed to ensure retrievability. The indexing system shall include:

3.8.2.A Location of the records within the records management system.

3.8.2.B Identification of the item or related activity to which the records pertain.

3.8.2.C Classification of the record.

3.8.3 Records shall be submitted to storage after processing has been completed.

3.8.4 Access to storage facilities shall be controlled.

3.8.5 A list shall be maintained designating personnel who are permitted access to the records.

3.8.6 The record management system shall provide for retrieval of records with planned retrieval times based on record type.

### 3.9 Correcting Information in Records

3.9.1 Corrections to records including documents that will become records shall include the initials or signature of the person authorized to make the correction and the date the correction was made.

3.9.2 Corrections to records shall be approved by the originating organization.

3.9.3 If an organization that was originally responsible for approving a particular document is no longer responsible, the new responsible organization shall be identified.

3.9.4 When correction to a record is required, a single line shall be drawn through the information to be corrected. The individual revising the information shall initial and date the revision adjacent to the drawn line. Erasers or correction fluid or tapes shall not be used. Corrections, when required, shall be recorded adjacent to the information to be corrected or by recording the referenced location of the correction. Correction to authenticated records shall be resubmitted to the originating organization (or designee) for authentication. The implementing records procedures shall address the editorial correction of records.

3.9.5 Correction to an electronic record will be in accordance with established procedures.

### 3.10 Replacement of Records

3.10.1 Organizations originating records shall develop implementing documents that identify means for replacement, restoration, or substitution of lost or damaged records.

3.10.2 Lost or damaged records shall be replaced or restored. When replacement or restoration cannot be achieved, the owning organization shall conduct and document an evaluation of the impact.

## 4 Specific DOE/RW-0333P QARD Requirements for IHLW Applications

In addition to the requirements found in section 3 of this Policy, the following requirements are applicable to High Level Waste activities and shall be implemented.

### 4.1 Classification of Records

4.1.1 Documents that meet the following requirements shall be classified as lifetime records:

4.1.1.A Documents that provide evidence of the quality of items.

4.1.1.B Documents that provide evidence of the quality of activities related to items.

4.1.1.C Documents that provide evidence of those activities that provide data used to assess the potential dispersion of radioactive materials from the licensed facility.

4.1.1.D Documents that provide evidence of the quality of the production process for the high-level waste form and acceptance of the high-level waste form itself.

4.1.1.E Personnel training and qualification documents for individuals executing program requirements.

4.1.1.F Documents which are implementing documents as described in Policy Q-05.1 - *Instructions, Procedures and Drawings*.

# 5 Records

5.1 Records designated in implementing documents as quality assurance records shall be controlled in accordance with this policy.

# 6 Responsibilities

## 6.1 Quality Assurance Manager

6.1.1 The QA Manager is responsible for developing, maintaining, and interpreting the requirements of this policy.

## 6.2 Project Administrative Services Manager

6.2.1 The Project Administrative Services Manager is responsible for developing and maintaining a records management system and procedures that implement these requirements.

## 6.3 Personnel

6.3.1 All Personnel are responsible for carrying out requirements set forth in this policy, and for following the implementing procedures that define and control records. In addition, personnel handling records shall protect them from damage or loss until the records are submitted to the records management system.

# Policy Q-18.1 Independent Assessment (Audit)

## 1 Purpose and Applicability

1.1 This policy identifies requirements and responsibilities for performing independent assessments (audits), both internal and external. Assessments are used to verify compliance with and to determine the effectiveness of the quality assurance (QA) program implementation and maintenance, and to identify continuous improvement opportunities.

1.2 The audited organization's management shall on a continuing basis, be apprised of the status, adequacy, and compliance aspects of the QA program. Appropriate management shall conduct and receive assessment reports.

1.3 This policy applies to those organizations involved in or subject to the performance of independent assessment audits.

## 2 Implementation Strategy

2.1 Independent audits/assessments are to be planned and conducted to measure item and service quality; to measure the adequacy of work performance; and to promote improvement. Independent audits are an important element of the feedback and improvement mechanism of the Integrated Safety Management System (ISMS). Audits will be conducted to evaluate the performance of work processes and to promote improvement with regard to requirements and management expectations. The focus of audits includes emphasis on results, technical adequacy, and the quality or work processes. Audits are to be performed by the trained and qualified personnel from the QA organization augmented as necessary by trained technical specialists as appropriate for the area being audited. These audits are separate from, and in addition to, surveillances identified in Policy Q-18.2 - *Quality Assurance Surveillance* and Management Assessments identified in Policy Q-18.3 - *Management Assessments*.

2.2 Documented independent audits are to be routinely planned, scheduled, and conducted to verify conformance of items, services, and processes to established requirements of the 18 plus policies of this manual and applicable project technical standards and other procedural or process requirements. The schedules, and the allocation of resources needed to meet these schedules, are to be based on the status, hazard, and complexity of the activity or process being assessed. Schedule flexibility will allow performance of additional audits in questionable areas. The audit process will include follow-up by project management to assure corrective action is implemented when deficiencies are identified.

2.3 Audit results are to be tracked and individuals in management responsible for their resolution clearly assigned. The need for follow-up review of areas found deficient during an audit will be determined by the QA Manager or designee. Conditions adverse to quality identified during the audit process will be dispositioned by the responsible organization in accordance with either Policy Q-15.1 - *Control of Nonconforming Items,* or Policy Q-16.1 - *Corrective Action*, as appropriate.

2.4 Independent audit personnel will act in a management advisory capacity. Audits are to be performance-based with emphasis on results and with compliance viewed as the baseline.

2.5 Performance-based audits, focusing on items, services, and process improvement, will evaluate and report on the organization's achievement of quality and the effectiveness of the organization's management assessment programs. During the conduct of performance-based assessments, work will be monitored to identify problems, abnormal performance, and to promote improvement. Strengths and weaknesses (opportunities for improvement) affecting the quality of services and process should be identified so that meaningful action can be taken by responsible management to improve the process or service. Audit results are to be documented and provided to a level of management having the authority to implement necessary corrective actions and verify that identified problems have been satisfactorily resolved.

2.6 The qualification of independent audit personnel is specified in Policy Q-02.3 - *Auditor/Lead Auditor Qualification and Certification.* The group performing independent audits will have sufficient authority and freedom from the line to carry out its responsibilities. Personnel performing independent audits will not have direct responsibilities in the area they are assessing. Participation by individuals (technical specialists) outside the project may be used to complement the independent assessment program.

2.7 Procedure(s) for conducting independent audits are to be developed by the QA organization utilizing the requirements of this policy.

# 3 Policy

## 3.1 Audits

3.1.1 Audits shall be performed to verify that performance criteria are met and to determine the effectiveness of the program.

3.1.2 The lead auditor organizes and directs audits, reports audit findings, and evaluates corrective actions.

## 3.2 Scheduling Internal Audits

3.2.1 Internal audits shall be scheduled in a manner to provide coverage, consistency, and coordination with on-going work.

3.2.2 Internal audits shall be scheduled at a frequency commensurate with the status and importance of the work.

3.2.3 Internal audits shall be scheduled to begin as early in the life of the work as practical, and shall be scheduled to continue at intervals consistent with the schedule for accomplishing the work.

**Policy Q-18.1 Independent Assessment (Audit)**

3.2.4 Regularly scheduled internal audits shall be supplemented by additional audits of specific subjects when necessary to provide an adequate assessment of compliance or effectiveness.

3.2.5 Internal audits to determine QA program effectiveness (performance based audits) shall be performed on selected work.

3.2.6 An annual audit schedule will be developed, reviewed periodically, and revised as necessary to ensure that the QA program coverage is current.

## 3.3 Scheduling External Audits

3.3.1 The need for and frequency of external audits shall be determined after the supplier has been selected to perform work. The determination shall be based on the complexity and nature of the items or services being procured.

3.3.2 External audits shall not be required for procured items that are relatively simple and standard in design, manufacturing, and testing, or adaptable to standard or automated inspections or tests of the end item to verify quality characteristics after delivery. The rationale for not performing audits for these items shall be documented.

3.3.3 The need to schedule additional external audits shall also be evaluated when a major change in the contract scope, work methodology, or organization occurs.

3.3.4 The audit schedule shall be developed annually and revised periodically to ensure that coverage is maintained current.

## 3.4 Audit Planning

3.4.1 The auditing organization shall develop and document an audit plan for each scheduled audit.

3.4.2 The audit plan shall identify the audit scope, requirements for performing the audit, type of audit personnel needed, activities to be audited, organizations to be notified, applicable documents, schedule, and written implementing documents or checklists to be used.

3.4.3 Audits shall include technical evaluations of the applicable procedures, instructions, activities, and items.

3.4.4 The scope of each audit shall be based on evaluation of implementing documents, activities, and items to be audited, the results of previous audits, and the impact of significant changes in personnel, organization, or the QA program.

## 3.5 Audit Team Independence

3.5.1 Audits shall be performed in accordance with written procedures or checklists by personnel who do not have direct responsibility for performing the activities being audited.

3.5.2 Audit personnel shall have sufficient authority and organizational freedom to make the audit process meaningful and effective.

## 3.6 Selection of the Audit Team

3.6.1 An audit team shall be identified prior to the beginning of each audit, and shall not be selected by personnel having direct responsibility for the work to be audited, or include personnel responsible for the work being audited.

3.6.2 The audit team shall include representatives from the QA organization, and when appropriate, applicable technical organizations.

3.6.3 The audit team shall contain one or more auditors, one being designated the lead auditor who supervises the team, organizes and directs the audit, coordinates the preparation and issuance of the audit report, and evaluates responses.

3.6.4 Lead auditors and auditors shall be qualified in accordance with the requirements of Policy Q-02.3 - *Auditor/Lead Auditor Qualification and Certification*.

3.6.5 Technical specialists may be used by the auditing organization to assist in assessing the adequacy of technical processes.

3.6.6 Technical specialists, when used, shall be indoctrinated, trained and qualified in accordance with the requirements of Policy Q-02.2 - *Personnel Training and Qualification*, and Policy Q-02.3 - *Auditor/Lead Auditor Qualification and Certification*.

3.6.7 The lead auditor shall, before starting the audit, ensure that the assigned personnel collectively have experience or training commensurate with the scope, complexity, or special nature of the work to be audited.

## 3.7 Performing Audits

3.7.1 The audit team leader shall ensure that the audit team is prepared before starting the audit.

3.7.2 Audits shall be performed in accordance with written procedures or checklists.

3.7.3 Elements selected for audit shall be evaluated against specified requirements.

3.7.4 Objective evidence shall be examined to the depth necessary to determine if these elements are being implemented effectively.

3.7.5 Audit results shall be documented and reported to and reviewed by responsible managers.

3.7.6 Conditions requiring prompt corrective action shall be reported immediately to management of the audited organization.

3.7.7 Identified conditions adverse to quality shall be documented and corrected in accordance with Policy Q-16.1 - *Corrective Action*.

3.7.8 Nonconforming items identified during an audit shall be controlled by the audited organization in accordance with Policy Q-15.1 - *Control of Nonconforming Items*.

### 3.8 Reporting

3.8.1 The lead auditor is responsible for preparing and signing the audit report and issuing the report to the audited organization and impacted organizations.

3.8.2 The audit report shall:

3.8.2.A Describe the audit scope.

3.8.2.B Identify auditors and persons contacted.

3.8.2.C Summarize audit results, documents reviewed, persons interviewed, (and the specific results of the reviews and interviews, that is, a summary of the checklist contents) issuing a statement on the effectiveness of the elements audited.

3.8.2.D Describe each reported adverse audit finding in sufficient detail to enable corrective action to be taken by the audited organization in accordance with Policy 16.1 - *Corrective Action*.

### 3.9 Response

3.9.1 Management of the audited organization or activity shall investigate adverse audit findings, determine and schedule corrective action, including measures to prevent recurrence of significant conditions adverse to quality, and notify the appropriate organization in writing of the actions taken or planned.

3.9.2 The adequacy of corrective actions for conditions adverse to quality shall be evaluated by the auditing organization in accordance with the requirements of Policy Q-16.1 - *Corrective Action*.

### 3.10 Follow-Up Action

3.10.1 Follow-up action shall be taken by the auditing organization to verify that corrective action is accomplished as scheduled in accordance with the requirements of Policy Q-16.1 - *Corrective Action*.

## 4 Specific DOE/RW-0333P QARD Requirements for IHLW Applications

In addition to the requirements found in section 3 of this Policy, the following requirements are applicable to High Level Waste activities and shall be implemented.

4.1 Internal audits of work to verify QA program compliance shall be performed annually or at least once during the life of the work, whichever is shorter.

4.2 External audits for compliance shall be performed triennially, as a minimum, with the initial audit to occur as early in the life of the activity as practical.

4.3 The need to schedule additional external audits shall also be evaluated when a major change in the contract scope, work methodology, or organization occurs.

4.4 Pre-award surveys, if applicable, may serve as the first triennial audit, provided:

4.4.1 The supplier is implementing the same QA program for other contracts that is proposed for the purchasers contract,

4.4.2 The pre-award survey satisfies the same audit elements and criteria as those used in the performance of a triennial audit.

4.5 External audits to determine QA program effectiveness (performance based audits) shall be performed on selected work.

4.6 Annual performance evaluations shall be performed on each supplier to determine the need to schedule additional audits. The evaluation shall be documented and based on:

4.6.1 Review of documentation furnished by the supplier (such as certificates of conformance, nonconformance notices, and corrective actions).

4.6.2 Results of previous source verification audits, management assessments and receiving inspections, including audits from other sources.

4.6.3 Operating experience of identical or similar work furnished by the same supplier.

4.6.4 A review of procurement documents to determine what additional work the supplier has received since the initial contract.

# 5 Records

5.1 All records designated in implementing documents as quality assurance records shall be controlled in accordance with Policy Q-17.1 - *Quality Assurance Records.*

5.2 Audit records shall include audit plans, audit reports, written responses, and the record of completion of corrective action.

# 6 Responsibilities

## 6.1 Quality Assurance Manager

6.1.1 The QA Manager is responsible for:

6.1.1.A Conducting audits using personnel qualified/certified per Policy Q-02.3 - *Auditor/Lead Auditor Qualification and Certification.*

6.1.1.B Implementing an effective audit program.

6.1.1.C Developing and distributing audit schedules.

6.1.1.D Ensuring implementation of corrective actions are verified in a timely manner.

6.1.1.E Establishing and maintaining a site wide schedule for all required external supplier audits.

6.1.1.F Performing external supplier audits to evaluate supplier conformance with approved contractual requirements.

6.1.1.G Establishing and implementing a supplier qualification and/or requalification process.

6.1.1.H Ensuring that the auditors are independent of the work being audited.

## 6.2 Audited Organizations

6.2.1 Audited organizations are responsible for:

6.2.1.A Providing audit personnel with reasonable and timely access to the facilities, documents, and personnel needed for planning and performing audits.

6.2.1.B Providing responses to findings that describe the actions taken (or planned) in order to correct the problem and prevent recurrence.

6.2.1.C Providing for access by auditor(s)/lead auditor to appropriate levels of management to ensure resolution of audit findings.

6.2.1.D Implementing corrective actions within specified time frames identified in responses to findings.

6.2.1.E Demonstrating support for the audit process through management involvement in audits.

# Policy Q-18.2 Quality Assurance Surveillance

## 1 Purpose and Applicability

1.1 This policy identifies requirements and responsibilities for performing quality assurance surveillances, both internal and external. Surveillances are used to evaluate the adequacy, effectiveness, and compliance to specified requirements, quality assurance (QA) program implementation and maintenance, and to identify continuous improvement opportunities.

1.2 This policy applies to those organizations involved in or subject to the performance of QA surveillances.

## 2 Implementation Strategy

2.1 Surveillance activities can be planned and/or conducted at any time on any activity to measure item and service quality; to measure the adequacy of work performance; and to promote improvement. Surveillances are an important element of the feedback and improvement function of the Integrated Safety Management System (ISMS). Surveillances are to be performed by the QA organization. Surveillance activities are separate from, and in addition to, the independent and management assessments. These documented surveillances are to be routinely conducted to verify conformance of items, services, and processes to established requirements. Flexibility in conducting surveillances will allow performance of additional surveillances in questionable areas. The surveillance process will include follow-up by project management to assure corrective action is implemented when deficiencies are identified in accordance with either Policy Q-15.1 - *Control of Nonconforming Items* or Policy Q-16.1 - *Corrective Action*, as appropriate.

2.2 The need for follow-up review of areas found deficient during a surveillance will be determined by the QA organization. Conditions adverse to quality identified during the surveillance process will be dispositioned by the responsible organization in accordance with either Policy Q-15.1- *Control of Nonconforming Items* or Policy Q-16.1 - *Corrective Action*, as appropriate.

2.3 Opportunities for improvement can be identified by the surveillance process. Surveillance results are to be documented and provided to a level of management having the authority to implement necessary corrective actions and verify that identified problems have been satisfactorily resolved.

2.4 Procedure(s) for conducting surveillances are to be developed by the QA organization utilizing the requirements of this policy.

## 3 Policy

### 3.1 Surveillances

3.1.1 Surveillances shall be conducted to:

3.1.1.A Verify the quality of work in progress and compliance with applicable governing documents.

3.1.1.B Identify conditions adverse to quality.

3.1.1.C Ensure that prompt corrective action is taken by management responsible for performing the work.

3.1.1.D Verify the timely implementation, adequacy, and effectiveness of corrective action.

3.1.2 Surveillances shall be performed by personnel who are technically knowledgeable about, and not directly responsible for, the work under surveillance. Such personnel shall have sufficient authority and independence from the work activity to carry out their responsibilities.

3.1.3 Surveillances shall be documented in a report to appropriate management.

3.1.4 Surveillances shall be conducted to evaluate the quality of selected work subject to this policy.

# 4 Specific DOE/RW-0333P QARD Requirements for IHLW Applications

4.1 All applicable DOE/RW-0333P QARD requirements are included in subsection 3 - *Policy*.

# 5 Records

5.1 All records designated in implementing documents, as QA records shall be controlled in accordance with Policy Q-17.1 - *Quality Assurance Records*.

# 6 Responsibilities

## 6.1 Quality Assurance Manager

6.1.1 The QA Manager is responsible for:

6.1.1.A Planning, scheduling, and performing surveillances.

6.1.1.B Trending the results of surveillances.

6.1.1.C Assigning technically qualified personnel to perform surveillances.

6.1.1.D Providing the flexibility to conduct spontaneous, unscheduled surveillances to respond to immediate needs.

## 6.2 Organizations

6.2.1 Organizations are responsible for:

**Policy Q-18.2 Quality Assurance Surveillance**

6.2.1.A Providing reasonable and timely access for surveillance personnel to review work activities and areas.

6.2.1.B Implementing corrective actions within the specified time.

6.2.1.C Providing responses to surveillance reports describing actions to be taken to correct discrepant conditions, which could not be corrected during the surveillance (on the spot), and the scheduled completion date for any corrective actions required.

# Policy Q-18.3 Management Assessment

## 1 Purpose and Applicability

1.1 This policy identifies requirements and responsibilities for establishing and performing periodic management assessments of the adequacy of implementation of management process within their respective organizations.

1.2 This policy applies to all levels of project management and provides for their direct involvement in planning and conducting assessments to determine how well their organizations are performing in achieving strategic goals and performance objectives aligned with meeting customer requirements and expectations.

## 2 Implementation Strategy

2.1 Management Assessment implements, in part, the Integrated Safety Management System (ISMS) core function of feedback and improvement and demonstrates ISMS guiding principles of management responsibility, continuous improvement, and senior management involvement. Project management will use management assessment processes to evaluate the adequacy and effectiveness of its management control systems for improving processes and eliminating barriers to achieving project goals and objectives. Management participation in these assessment efforts is mandated by the Project Director. While retaining overall responsibility for the assessment process, senior management requires managers at all levels to foster the continuous improvement process by assessing the performance of the activities assigned to their organization.

2.2 Such assessments are to be planned and performed as an on-going activity to verify conformance to applicable requirements and identify opportunities to improve performance and cost-effectiveness. Results and conclusions from these assessments will be documented and evaluated at the organizational level to assess the effectiveness of the entire integrated management system on achieving established goals and objectives, and fostering the continuous improvement process. Conditions adverse to quality identified in management assessments are to be promptly and effectively resolved as required by Policy Q-16.1 - *Corrective Action*. Provisions are to include tracking and follow-up on completed and planned corrective actions from the assessments.

2.3 Management assessments will utilize an evaluation process to examine project performance, with particular emphasis on areas or activities that could have an adverse impact on worker and public safety or on the environment. The process should include activities for evaluating conditions as, for example, employee knowledge and morale, communications, material resources, and project documentation. Management from each organization will have the prime responsibility for planning and conducting such assessments. Deficiencies, as well as, opportunities for improvement, are to be identified and action plans developed and implemented where appropriate.

2.4 Management assessments are part of the feedback and improvement function of the Project ISMS. Management assessments are implemented utilizing approved procedures based on the requirements of this policy.

# 3 Policy

## 3.1 Management Assessments

3.1.1 Management shall regularly assess the adequacy and effective implementation of their management processes. Problems that hinder the organization from achieving its objectives shall be identified and corrected.

3.1.2 Procedures shall be in place and followed for the conduct of management assessments.

3.1.3 Management assessments are to be conducted at reasonable intervals not to exceed 12 months.

3.1.4 Management assessment shall:

3.1.4.A Be planned and documented and performed annually.

3.1.4.B Evaluate the following:

3.1.4.B.1. Adequacy of resources and personnel provided to achieve and assure quality.

3.1.4.B.2. Adequacy of procedure content and coverage.

3.1.4.B.3. Effectiveness of procedure implementation.

3.1.5 Management assessments shall be documented and results distributed to the appropriate management.

3.1.6 Conditions adverse to quality identified during the assessment process must be dispositioned in accordance with either Policy 15.1 - *Nonconforming Items* or Policy Q-16.1 - *Corrective Action* as appropriate.

## 3.2 Records

3.2.1 All records designated in implementing documents as quality assurance records shall be controlled in accordance with Policy Q-17.1 - *Quality Assurance Records*.

# 4 Specific DOE/RW-0333P QARD Requirements for IHLW Applications

4.1 All applicable DOE/RW-0333P QARD requirements have been included in subsection 3 – *Policy*.

# 5 Responsibilities

## 5.1 Project Management

5.1.1 Project Management is responsible for:

5.1.1.A Implementing the management assessment program.

## 5.2 Managers

5.2.1 All levels of management are responsible for participating in management assessments.

# Appendix A Quality Assurance Manual Acronyms and Abbreviations

| | |
|---|---|
| AB | Authorization Bases |
| ALARA | as low as reasonably achievable |
| ANSI | American National Standards Institute |
| ASME | American Society of Mechanical Engineers |
| ASL | Approved Suppliers List |
| ASTM | American Society of Testing and Materials |
| BNI | Bechtel National, Inc. |
| CFR | Code of Federal Regulations |
| CI | counterfeit items |
| CM | configuration management |
| DEAR | DOE Acquisition Regulation |
| DOE | Department of Energy |
| DQO | data quality objective |
| EPA | Environmental Protection Agency |
| E&NS | Environmental, and Nuclear Safety |
| EPC | engineering, procurement, and construction |
| ET | electromagnetic testing |
| FSP | field sampling plan |
| GED | general equivalency diploma |
| I&C | instrumentation and control |
| IHLW | Immobilized High-Level Waste |
| ILAW | Immobilized Low-Activity Waste |
| IPI | Installed Process Instrumentation |
| ISI | in-service inspection |
| ISMS | Integrated Safety Management System |
| ISO | International Standards Organization |
| LT | leak testing |
| M&TE | measuring and test equipment |
| MT | magnetic particle testing |
| NCR | nonconformance report |

**Appendix A Quality Assurance Manual Acronyms and Abbreviations**

| | |
|---|---|
| NDE | nondestructive examination |
| OCRWM | Office of Civilian Radioactive Waste Management |
| ORR | Operational Readiness Reviews |
| PAAA | Price Anderson Amendment Act of 1988 |
| PM | project manager |
| PSC | Project Safety Committee |
| PT | liquid penetrant testing |
| QA | quality assurance |
| QAM | Quality Assurance Manual |
| QAP | quality assurance program |
| QAPjP | Quality Assurance Project Plans |
| QARD | Quality Assurance Requirement Document |
| QC | Quality Control |
| RCRA | Resource Conservation and Recovery Act of 1988 |
| RT | radiographic testing |
| RW | radioactive waste |
| S/CI | suspect/counterfeit item |
| SAP | sampling and analysis plan |
| SME | subject matter expert |
| SNT | Society for Nondestructive Testing |
| SOW | statement of work |
| SSC | systems, structures, components |
| STD | standard |
| UL | Underwriters Laboratory |
| UOR | Unusual Occurrence Report |
| UT | ultrasonic testing |
| VT | visual testing |
| WAC | Washington Administrative Code |
| WAP | waste analysis plan |
| WGI | Washington Group International |
| WTP | Hanford Tank Waste Treatment and Immobilization Plant project |

# Supplement I Control of the Electronic Management of Data

## 1 Purpose

1.1 This supplement applies to the processes and controls for the management of data that either exist or are used in an electronic format. This includes electronic formatted data used in design input, developed as design output, or developed as an output of scientific investigation or performance assessment modeling and analysis.

1.2 Development of software including database applications or software that performs functions of analysis or calculation shall be controlled in accordance with Policy Q-03.2 - *Software Quality*. The acquisition, development, and use of data are controlled by the requirements of Policy Q-03.1 - *Design Control.*

## 2 Applicability

2.1 This policy applies to organizations involved in the control of the electronic management for elements that affect the Immobilized High-Level Waste (IHLW) product quality, including but not limited to, waste form development, qualification, characterization, production process control, certification, and storage of the IHLW. All IHLW research and technology activities shall be conducted in accordance with the Quality Assurance (QA) Manual and this supplement.

## 3 Policy

### 3.1 Control of the Electronic Management of Data

3.1.1 Procedures will be established for process controls to ensure:

3.1.1.A Data are suitably protected from damage and destruction during their prescribed lifetime and are readily retrievable.

3.1.1.B A description is prepared of how data will be stored with respect to media, conditions, location, retention time, security, and access.

3.1.1.C Storage and transfer media are properly identified as to source, physical and logical format, and relevant date (i.e., date written).

3.1.1.D The completeness and accuracy of the data input and any subsequent changes to the data are maintained.

3.1.1.E The security and integrity of the data are maintained.

3.1.1.F Data transfers are error free, or within a defined permissible error rate, to ensure no information is lost in transfer and that the input is recoverable from the output. Examples of data transfer include copying raw data from a notebook to a computerized data form, copying from computer tape to disk, etc.

# 4 Records

4.1 Records requirements of this supplement are contained in Policy Q-03.1 – *Design Control*, Policy Q-03.2 – *Software Quality*, and Policy Q-17.1 – *Quality Assurance Records*.

# 5 Responsibilities

## 5.1 Manager of Engineering

5.1.1 The Manager of Engineering is responsible for incorporating the requirements of this supplement into applicable research and technology, design control, and software quality procedures.

## 5.2 Quality Assurance Manager

5.2.1 The QA Manager is responsible for reviewing and concurring with the procedures developed for implementing the requirements of this supplement.

# Supplement II Sample Control

## 1 Purpose

1.1 This supplement establishes requirements for the control of physical samples.

## 2 Applicability

2.1 This policy applies to organizations involved in sampling for elements that affect the Immobilized High-Level Waste (IHLW) product quality, including but not limited to, waste form development, qualification, characterization, production process control, and certification of the IHLW. All IHLW research and technology activities shall be conducted in accordance with the Quality Assurance (QA) Manual and this supplement.

## 3 Policy

### 3.1 General

3.1.1 Samples shall be controlled and identified in a manner consistent with their intended use.

3.1.2 These controls shall identify responsibilities including interfaces between organizations for documenting and tracking sample possession from sample collection and identification through handling, preservation, shipment, transfer, analysis, storage, and final use.

3.1.3 Controls shall include specifics on orientation relative to the location that was sampled, as appropriate.

### 3.2 Traceability

3.2.1 Sample identification methods shall ensure that traceability is established and maintained from the samples to applicable implementing documents or other specifying documents.

3.2.2 Sample traceability shall ensure that the sample can be traced at all times from its collection through final use.

### 3.3 Identification

3.3.1 Identification shall be maintained on the samples or in a manner which ensures that identification is established and maintained.

3.3.2 Samples shall be identified from their initial collection through final use.

3.3.3 Sample identification is documented and checked before released for use.

3.3.4 Sample identification methods shall include use of physical markings.

3.3.5 If physical markings are either impractical or insufficient, other appropriate means shall be employed (such as physical separation, labels or tags attached to containers, or procedural control).

3.3.6 Physical markings, when used, shall:

3.3.6.A Be applied using materials and methods that provide a clear and legible identification.

3.3.6.B Not detrimentally affect the sample content or form.

3.3.6.C Be transferred to each identified sample part when the sample is subdivided.

3.3.6.D Not be obliterated or hidden by surface treatments or sample preparations unless other means of identification are substituted.

## 3.4 Conditional Requirements

3.4.1 The controls for samples shall address the following requirements, as applicable:

3.4.1.A If documents (such as the Site Characterization Plan, test plans, study plans, or job packages) contain specific identification or traceability requirements (such as identification or traceability of the sample to applicable study plan, site characterization activity, or other records), those specified controls shall be implemented.

3.4.1.B If samples have limited use or storage life, then methods shall be established that preclude using the sample beyond its intended use or storage life.

3.4.1.C If sample storage is required, then methods shall be established for the control of sample identification that are commensurate with the planned duration and conditions of storage. These methods shall provide for, as applicable:

3.4.1.C.1. Maintenance or replacement of markings and identification tags damaged during handling or aging.

3.4.1.C.2. Protection of identification markings subject to excessive deterioration resulting from environmental exposure.

3.4.1.C.3. Updating related documentation.

## 3.5 Archiving Samples

3.5.1 Implementing documents shall specify the representative samples to be archived if the need to archive samples is identified.

### 3.6 Handling, Storage, and Shipping

3.6.1 Handling, storage, cleaning, packaging, shipping, and preservation of samples shall be conducted in accordance with established implementing documents or other specified documents.

3.6.2 If required for critical, sensitive, perishable, or high-value samples, specific measures for handling, storage, cleaning, packaging, shipping, and preservation shall be identified and used.

3.6.3 Measures shall be established for the marking and labeling for packaging, shipping, handling, and storage of samples as necessary to adequately identify, maintain, and preserve the sample.

3.6.4 Markings and labels shall indicate the presence of special environments or the need for special controls if necessary.

3.6.5 If required for particular samples, special equipment (such as containers) and special protective environments (such as inert gas, and moisture and temperature limits) shall be specified and provided.

3.6.6 Special handling tools and equipment shall be used and controlled as necessary to ensure safe and adequate handling.

3.6.6.A Special handling tools and equipment shall be inspected and tested in accordance with implementing documents and at specified time intervals to verify that the tools and equipment are adequately maintained.

3.6.6.B Operators of special handling and lifting equipment shall be experienced or trained to use the equipment.

### 3.7 Disposition of Nonconforming Samples

3.7.1 Samples that do not meet requirements specified in work controlling documents (such as Job Packages, Travelers, or Work Requests) shall be documented, evaluated, identified, and segregated in accordance with Policy Q-15.1 - *Control Of Nonconforming Items*.

3.7.2 The disposition for nonconforming samples shall be identified and documented and shall be limited to "use-as-is", "limited use", or "discard".

## 4 Records

4.1 Records of samples for IHLW product quality, including, but not limited to, waste form development, qualification, characterization, production process control, and certification of IHLW shall be maintained in accordance with this policy and Policy Q-17.1 – *Quality Assurance Records*.

# 5 Responsibilities

## 5.1 Operations Manager

5.1.1 The Operations Manager is responsible for developing the necessary procedure(s) that implement the requirements of this supplement.

## 5.2 Quality Assurance Manager

5.2.1 The QA Manager is responsible for reviewing and concurring with the procedures developed for implementing the requirements of this supplement.

# Supplement III Scientific Investigation

## 1 Purpose

1.1 This policy establishes requirements for scientific investigations, including data identification, data reduction, and model development and use.

## 2 Applicability

2.1 This policy applies to organizations involved in scientific investigation for elements that affect the Immobilized High-Level Waste (IHLW) product quality, including but not limited to, waste form development, qualification, characterization, production process control, and certification of the IHLW. All IHLW research and technology activities shall be conducted in accordance with the Quality Assurance (QA) Manual and this supplement.

## 3 Policy

### 3.1 Planning Scientific Investigations

3.1.1 Scientific investigations shall be planned in accordance with Policy Q-02.1 – subsection 1.5 – *Work Planning.*

3.1.2 Planning shall be coordinated with organizations providing input to or using the results of the investigation.

3.1.3 Planning shall address provisions for determining the accuracy, precision, and representativeness of results.

### 3.2 Performing Scientific Investigations

3.2.1 Scientific investigations shall be performed using scientific notebooks, implementing documents, or a combination of both.

3.2.2 Scientific notebooks shall contain the following:

3.2.2.A Statement of objective and description of work to be performed, or reference to an approved planning document or implementing document that addresses those topics.

3.2.2.B Identification of method(s) and computer programs to be used.

3.2.2.C Identification of any samples or measuring and test equipment used.

3.2.2.D Description of the work as it was performed and results obtained, names of individuals performing the work, and dated initials or signature, as appropriate, of individuals making the entries.

3.2.2.E Description of changes made to methods used, as appropriate.

3.2.3 Scientific notebooks shall be reviewed by an independent qualified individual to verify there is sufficient detail to:

3.2.3.A Retrace the investigations and confirm the results, or

3.2.3.B Repeat the investigation and achieve comparable results, without recourse to the original investigator.

## 3.3 Data Identification

3.3.1 Data shall be identified in a manner that facilitates traceability to associated documentation.

3.3.2 Data shall be identified in a manner that facilitates traceability to its qualification status.

3.3.3 Identification and traceability shall be maintained throughout the lifetime of the data.

## 3.4 Data Review, Adequacy, and Usage

3.4.1 Data reduction shall be described to permit independent reproducibility by another qualified individual.

3.4.2 Data that are directly relied upon to address safety and waste isolation issues shall be qualified data or established fact, except as allowed in 3.4.2.C.

3.4.2.A Data shall be reviewed by individuals other than those who reduced the data to ensure technical correctness.

3.4.2.B Unqualified data may be used in scientific investigation and design activities, provided traceability to its status as unqualified data is maintained. Unqualified data directly relied upon to address safety and waste isolation issues shall be qualified in accordance with 3.4.C below at appropriate times during scientific investigation and design process and before:

3.4.2.B.1. Office of Civilian Radioactive Waste Management (OCRWM) acceptance of DOE-owned high level waste;

3.4.2.B.2. Submittal of the license application;

3.4.2.B.3. Relying on the item for which the data were used as design input, to perform its function; or

3.4.2.B.4. Data are relied upon to resolve safety or waste isolation issues.

3.4.2.C Unqualified data directly relied upon to address safety and waste isolation issues shall be qualified by one or a combination of the methods that follow:

3.4.2.C.1. Determination that the controls under which the data were generated are similar in scope, requirements, and implementation to the QA Manual.

3.4.2.C.2. Evaluation of corroborating data - Rationale for selecting one set of data to corroborate another set of data shall be clearly explained and justified.

3.4.2.C.3. Confirmatory testing.

3.4.2.C.4. Peer review in accordance with Policy Q-02.4 – *Special Reviews.*

3.4.2.C.5. Technical Assessment to independently evaluate data which includes one or a combination of the following:

3.4.2.C.5.1. Determination that the employed methodology is acceptable;

3.4.2.C.5.2. Determination that confidence in the data acquisition or developmental results is warranted; or

3.4.2.C.5.3. Confirmation that the data have been used in similar applications.

3.4.3 Methods 1, 2, and 3 above shall include a review to determine the technical correctness of the data in accordance with established review criteria. The qualification process shall be planned and documented. Documentation shall include the acceptance criteria used to determine if the data are qualified, and rationale for discontinuing any qualification methods abandoned after the initiation of the qualification process.

## 3.5 Technical Report Review

3.5.1 Technical reports shall be reviewed in accordance with the requirements of Policy Q-05.1 – *Instructions, Procedures and Drawings*.

## 3.6 Model Development and Use

3.6.1 Model development and approaches to validation shall be planned, controlled, and documented. Planning for model validation shall identify the validation methods and the validation criteria used. If model validation activities will be completed after documentation of the model (for example, using new confirmation test data gathered in the field or laboratory), describe these activities in the work-planning document.

3.6.2 Documentation of models shall be in accordance with Policy Q-17.1 - *Quality Assurance Records*; shall be transparent; and shall include:

3.6.2.A Definition of the objective (intended use) of the model.

3.6.2.B Description of model and scientific basis, as well as alternatives for the selected model. Include rationale for not selecting alternatives.

3.6.2.C Results of literature searches and other applicable background data.

3.6.2.D Identification of inputs and their sources.

**Supplement III Scientific Investigation**

3.6.2.E Identification of and rationale for assumptions that are made to develop or apply the model, including model idealizations, as well as, those assumptions that support the developed data that are input to the model and impact model results.

3.6.2.F Discussion of mathematical and numerical methods that are used in the model, including governing equations, formulas, and algorithms, and their scientific and mathematical bases.

3.6.2.G Identification of any associated software used, computer calculations performed, and basis to permit traceability of inputs and outputs.

3.6.2.H Discussion of initial and/or boundary conditions.

3.6.2.I Discussion of model limitations (e.g., data available for model development, valid ranges of model application, spatial and temporal scaling).

3.6.2.J Discussion of model uncertainties (conceptual model, mathematical model, process model, abstraction model, system model, parameters) and how they affect the model.

3.6.2.K Identification of the originator, reviewer, and approver.

3.6.3 Computer software used to develop or execute the model shall be qualified in accordance with the requirements of the Policy Q-03.2 – *Software Quality*.

3.6.4 The intended use of the model and the importance of the model for assessing repository system performance shall determine the appropriate level of confidence for a model (i.e., models of system components most relied upon shall be validated with the highest levels of confidence to the extent practical).

3.6.5 Criteria for model validation shall be established to reduce, to the extent practical, the uncertainties inherent in the model and to demonstrate that the phenomenon, process, or system being represented by the model is sufficiently well understood to support the model's intended use. Model validation criteria shall address the following:

3.6.5.A Criteria used to establish the adequacy of the scientific basis for the model shall be consistent with the model application and justified in the model documentation.

3.6.5.B Criteria use to demonstrate that the model is sufficiently accurate for its intended use shall be consistent with parameter uncertainties and justified in the model documentation.

3.6.5.C Define the importance of the model for assessing repository system performance.

3.6.5.D Describe the relative level of confidence for the model.

3.6.5.E Define the supporting information needed to substantiate validation.

3.6.6 A model progression exists (usually from conceptual model to mathematical model to process model to abstraction model to system model). A conceptual model is validated when its implementation as a mathematical, process, abstraction, or system-level model is validated. Technical review through publication in a refereed professional journal or review by an external agency may be used to corroborate model validation when used in conjunction with one or more of the following:

3.6.6.A Corroboration of model results with data acquired from field experiments, analogue studies, laboratory experiments, or subsequent relevant observations (e.g., refereed journals or literature). Data used to develop and calibrate a model shall not be used to validate a model.

3.6.6.B Peer review and independent technical review.

3.6.6.C Performance confirmation studies using validation-test model predictions prior to comparison with field or laboratory data.

3.6.6.D Comparison of model results with other model results obtained from the implementation of an alternative conceptual model.

3.6.6.E Calibration with experimental data sets, including the review of model calibration parameters for reasonableness and consistency in explanation of all relevant data.

### 3.7 Implementing Documents

3.7.1 Implementing documents shall contain requirements for evaluating development and qualification results including final results within Waste Form Qualification Reports.

## 4 Records

4.1 Records requirements of this supplement are contained in Policy Q-03.1 – *Design Control,* Policy Q-03.2 – *Software Quality*, and Policy Q-17.1 – *Quality Assurance Records.*

## 5 Responsibilities

### 5.1 Manager of Engineering

5.1.1 The Manager of Engineering is responsible for incorporating the requirements of this supplement into applicable research and technology, design control, and software quality procedures.

### 5.2 Quality Assurance Manager

5.2.1 The QA Manager is responsible for reviewing and concurring with the procedures developed for implementing the requirements of this supplement.